

## Final Report

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# Presidential Advisory Committee on Gulf War Veterans' Illnesses

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## Presidential Advisory Committee on Gulf War Veterans' Illnesses

*Caring for veterans is not a partisan issue, it is a national obligation. . . They served their country with courage, skill and strength, and must now know that they can rely upon us. I pledge to our veterans and to every American, we will not stop until we have done all we can do to care for our Gulf War veterans.*

President Bill Clinton  
January 7, 1997

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Questions or comments? email: [lashofjc@gwvi.gov](mailto:lashofjc@gwvi.gov)

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**Presidential Advisory Committee on Gulf War Veterans' Illnesses  
Final Report**

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**MEMORANDUM**

TO: Secretary William Perry, Department of Defense  
Secretary Donna Shalala, Department of Health and Human Services  
Secretary Jesse Brown, Department of Veterans Affairs

RE: Final Report

DA: December 31, 1996

On behalf of the Presidential Advisory Committee on Gulf War Veterans' Illnesses, I am pleased to transmit our *Final Report*. Over the past 16 months, the Committee has analyzed the full range of the government's outreach, medical care, research, chemical and biological weapons, and coordination activities pertinent to Gulf War veterans' illnesses. We also investigated short- and long-term health effects of Gulf War risk factors.

Together with our February 1996 *Interim Report*, we make several recommendations we believe can improve our government's approach to addressing the concerns of the men and women who served our country during Operations Desert Shield/Desert Storm. We emphasize, however, that in the main these are suggestions to fine-tune the government's programs on Gulf War health matters. The Committee has concluded that in all areas save one, the government has responded with a comprehensive series of measures to address Gulf War veterans' illnesses.

Many veterans clearly are experiencing medical difficulties connected to their service in the Gulf War. First and foremost, continuing to provide clinical care to evaluate and treat veterans' illnesses is vital. At the same time, however, a causal link between a single factor and the symptoms Gulf War veterans currently report remains elusive. And while the Committee finds that stress is likely to be an important contributing factor to Gulf War veterans' illnesses, the story is by no means complete: Veterans, their physicians, and policymakers clearly stand to benefit from the broad array of ongoing research.

This benefit can only be achieved with a thoughtful, inclusive dialogue between veterans and your Departments. In light of public skepticism arising from recent revelations related to chemical weapons, the Committee strongly believes that a sustained risk communication effort is the only way to repair what many believe has been a breach of the government's compact with Gulf War veterans. This effort cannot begin soon enough.

The Committee is pained by the current atmosphere of government mistrust that now surrounds every aspect of Gulf War veterans' illnesses. It is regrettable-but also understandable. Our investigation of the Department of Defense's efforts related to chemical weapons led us to conclude these early efforts have strained public trust in our government. Hence, evidence of possible chemical warfare agent exposures during the Gulf War must be thoroughly evaluated by a group independent of DOD. This process must be conducted in an open manner and include veterans. The Committee recognizes that in November 1996 DOD announced it was expanding its efforts related to low-level CW agent exposure. These initiatives-combined with independent, vigorous oversight-could begin to restore public confidence in the government's investigations of possible incidents of CW agent exposure.

In closing, the Committee notes that in preparing this report, we relied on the generosity of hundreds of citizens committed to addressing concerns about Gulf War veterans' health. We gratefully acknowledge the significant time and effort that individuals within and outside government devoted to our effort-their contributions were invaluable.

Lastly, the Committee has been fortunate to have a talented and dedicated staff: This *Final Report* would not have been possible without them. The Committee members, staff, and I thank you for the unique opportunity to contribute to this critically important issue.

Joyce C. Lashof, M.D.  
Committee Chair

## **Presidential Advisory Committee on Gulf War Veterans' Illnesses Final Report**

### **EXECUTIVE SUMMARY**

President Clinton established the Presidential Advisory Committee on Gulf War Veterans' Illnesses in May 1995 to ensure an independent, open, and comprehensive examination of health concerns related to Gulf War service. The Committee, a 12-member panel made up of veterans, scientists, health care professionals, and policy experts, held 18 public meetings between August 1995 and November 1996. We heard invited testimony and received public comment at each meeting. Staff held in-house consultations, received briefings, conducted literature reviews, interviewed veterans, and reviewed government documents throughout our tenure. We analyzed information on the full range of activities specified in our charter—research, coordinating efforts, medical treatment, outreach, reviews conducted by other governmental and nongovernmental bodies, risk factors (exposure and health effects), and chemical and biological weapons—to reach our findings and recommendations. The *Final Report* presents the Committee's conclusions in three major parts:

- an evaluation of the government's response to Gulf War veterans' illnesses;
- an evaluation of available data on the nature of Gulf War veterans' illnesses; and
- an evaluation of available data on the health effects of Gulf War risk factors.

Findings and recommendations specific to the needs of Gulf War veterans appear throughout the *Final Report* and are summarized here.

The Committee's primary focus was on Gulf War veterans' illnesses, but parallels with the health concerns of Vietnam veterans became increasingly obvious over time. Thus, the Committee also decided to include in its analysis, recommendations on how to anticipate and avoid post-conflict health concerns.

### **ADDRESSING GULF WAR VETERANS' ILLNESSES**

Overall, the Committee is encouraged by the government's response to the range of health-related problems experienced by Gulf War veterans. We found the Vet Centers and Persian Gulf Family Support Program established by the Department of Veterans Affairs (VA) to be effective outreach programs and recommend that these field-based initiatives serve as models for health education and risk communication campaigns.

The Committee agrees with the Institute of Medicine's conclusion that the clinical evaluation programs of the Department of Defense (DOD) and VA are excellent for the diagnosis of Gulf War veterans' illnesses. We found some shortcomings in the availability of treatment, particularly with regard to mental health and reproductive health, and recommend better follow-up care in these areas.

The Committee found that the government's research portfolio is appropriately weighted toward epidemiologic studies and studies on stress-related disorders that are likely to improve our understanding of Gulf War veterans' illnesses. To close gaps in the current knowledge base, we recommend additional research on the long-term health effects of low-level exposures to chemical warfare agents and on the synergistic effects of pyridostigmine bromide—a chemical warfare agent pretreatment—with other Gulf War risk factors. We also recommend more emphasis on basic and applied research on the body's physical response to stress.

The existing knowledge base, including results from epidemiologic studies of Gulf War veterans, data from clinical evaluation and treatment programs for Gulf War veterans, and published literature from decades of toxicologic research, enabled the Committee to reach some conclusions about the nature and causes of Gulf War veterans' illnesses. We found that:

- among the subset of the Gulf War veteran population examined in the ongoing clinical and research programs, many veterans have illnesses likely to be connected to their service in the Gulf.
- current scientific evidence does not support a causal link between the symptoms and illnesses

reported today by Gulf War veterans and exposures while in the Gulf region to the following environmental risk factors assessed by the Committee: pesticides, chemical warfare agents, biological warfare agents, vaccines, pyridostigmine bromide, infectious diseases, depleted uranium, oil-well fires and smoke, and petroleum products.

- stress is known to affect the brain, immune system, cardiovascular system, and various hormonal responses. Stress manifests in diverse ways, and is likely to be an important contributing factor to the broad range of physical and psychological illnesses currently being reported by Gulf War veterans.

Currently, the extent of service-connected illness among Gulf War veterans is unknown, but the Committee anticipates results from the large, population-based epidemiologic studies now underway will shed light on this issue. In addition to the government's existing research, the Committee also recommends that mortality studies of Gulf War veterans continue, since some health effects, such as cancer, would not be expected to appear until a decade or more after the end of the Gulf War.

Although somewhat slow to act at the end of the Gulf War, the government is now providing appropriate medical care to Gulf War veterans and has initiated research in the areas most likely to illuminate the causes of their illnesses. The Committee identified ways to fine-tune those efforts, but found that, for the most part, the government has acted in good faith to address veterans' health concerns.

The Committee takes issue with the government's performance in one key area: investigation of possible exposures of U.S. troops to chemical

and biological warfare agents in the Gulf. We found substantial evidence of site-specific, low-level exposures to chemical warfare agents. Moreover, we found DOD's investigations to date superficial and unlikely to provide credible answers to veterans' and the public's questions. DOD's failure to seriously investigate chemical warfare agent exposures also adversely affected decisions related to funding research into possible health effects of low-level exposures to chemical warfare agents. At the Committee's final meeting in November 1996, DOD announced plans to revamp its investigatory and research programs related to low-level chemical warfare agent exposure. The Committee believes these efforts-combined with independent, high-quality oversight-could begin to restore public confidence in the government's investigations of possible incidents of chemical warfare agent exposure. Given that these steps come too late for the Committee to evaluate, however, we emphasize the importance of the following recommendation:

- To ensure credibility and thoroughness, further investigation of possible chemical or biological warfare agent exposures during the Gulf War should be conducted by a group independent of DOD. Openness in oversight activities-including public access to information and veteran participation-public notice of meetings, opportunity for public comment, and regular reporting are essential. Full public accountability is critical.

The government has a significant amount of ground to recover with Gulf War veterans and the American public, who have come to question whether a lack of data-on possible chemical warfare agent exposures, on the pre- or post-deployment health of veterans, or on the location of troops in-theater-indicates a lack of commitment to veterans' health. We recognize the many laudatory actions taken to address the concerns of Gulf War veterans, but the Committee believes the government can do a better job of anticipating and avoiding these types of problems. We offer the following findings and recommendations in that spirit.

## **AVOIDING POST-CONFLICT HEALTH CONCERNS**

The Committee was impressed by the professionalism of the individuals responsible for the government services we evaluated. We believe the expertise needed to improve technical performance and implement policy and procedural changes resides within the government, but we also believe that DOD and VA have much to learn from their peers in other agencies. Therefore, the Committee recommends that:

- A Presidential Review Directive (PRD) be issued to instruct the National Science and Technology Council (NSTC) to develop an interagency plan to address health preparedness for and readjustment of veterans and families after future conflicts and peacekeeping missions. The President's Committee of Advisors on Science and Technology and other nongovernmental experts, as appropriate, should be asked to review the plan 12 months after the PRD is issued and again at 18 months to ensure national expertise is brought to bear on these issues.

The NSTC's agenda should include the following recommendations for better communication, data, and services, which were developed during the Committee's evaluation of issues related to Gulf War veterans' illnesses (see *Final Report*, chapter 2 and chapter 4).

### **Better Communication**

Clearly, the volunteers who serve in defense of our Nation deserve complete and accurate information about the risks they face. An open democracy demands that the public, as well, has the opportunity to engage in policy debates that accompany the commitment of troops abroad. Therefore, the Committee recommends that:

- DOD and VA immediately develop and implement a comprehensive risk communication plan. This effort should move forward in close cooperation with agencies that have a high degree of public trust and experience with risk communication, such as the Agency for Toxic Substances and Disease Registry and the National Institute for Occupational Safety and Health.
- FDA solicit timely public and expert comment on any rule that permits waiver of informed consent for use of investigational products in military exigencies. Among the areas that specifically should be revisited are: adequacy of disclosure to service personnel; adequacy of recordkeeping; long-term followup of individuals who receive investigational products; review by an institutional review board outside of DOD; and additional procedures to enhance understanding, oversight, and accountability.

### **Better Data**

Many of the health concerns of Gulf War veterans may never be resolved fully because of the lack of data. The Committee identified problems related to missing medical records, the absence of baseline health data, inaccurate records of troop locations, and incomplete data on the health effects of what should have been viewed as reasonably anticipated risks. To help prevent similar problems in the future, we recommend that:

- DOD officials at the highest echelons, including the Joint Chiefs of Staff and the Commanders in Chief, assign a high priority to dealing with the problem of lost or missing medical records. A computerized central database is important. Specialized databases must be compatible with the central database. Attention should be directed toward developing a mechanism for computerizing medical data in the field (including classified information, if and when it is needed). DOD and VA should adopt standardized recordkeeping to ensure continuity.
- the Persian Gulf Veterans Coordinating Board and other appropriate departments and agencies be charged to develop a protocol to implement the following recommendation, which was made in the Committee's Interim Report: Prior to any deployment, DOD should undertake a thorough health evaluation of a large sample of troops to enable better postdeployment medical epidemiology. Medical surveillance should be standardized for a core set of tests across all services, including timely postdeployment followup.
- the government develop more accurate and reliable methods of recording troop locations to facilitate post-conflict health research. DOD should make full use of global positioning technologies.
- the government plan for further research on possible long-term health effects of low-level exposure to organophosphorus nerve agents such as sarin, soman, or various pesticides, based on studies of groups with well-characterized exposures, including: a) cases of U.S. workers exposed to organophosphorous pesticides; and b) civilians exposed to the chemical warfare agent sarin during the 1994 and 1995 terrorist attacks in Japan. Additional work should include followup and

evaluation of an appropriate subset of any U.S. service personnel who are presumed to be exposed during the Gulf War. The government should begin by consulting with appropriate experts, both governmental and nongovernmental, on organophosphorus nerve agent effects. Studies of human populations with well-characterized exposures will be much more revealing than studies based on animal models, which should be given lower priority.

- the government continue to collect and archive serum samples from U.S. service personnel when feasible.
- research on possible causes and methods of prevention of excess mortality from external causes among veterans receives high priority.
- the government consider methods for routinely sampling military populations regarding reproductive health so that an appropriate baseline exists for evaluating reproductive outcomes following deployment. In particular, DOD should consult with the National Center for Health Statistics and strongly consider implementing its National Survey of Family Growth and related methodologies for collecting data.
- the entire federal research portfolio place greater emphasis on basic and applied research on the physical effects of stress and on stress-related disorders.

### **Better Services**

The Nation has long provided care to veterans for service-connected health problems. Unfortunately, the government continues to give short shrift to veterans' legitimate concerns about reproductive health, and society at large continues to stigmatize mental health concerns. Therefore, the Committee recommends that:

the government conduct a thorough review of VA's policies concerning reproductive health and seek statutory authority to treat veterans and their families for service-connected problems. When indicated, genetic counseling should be provided-either via VA treatment facilities or referral-to assist veterans and their families who have reproductive concerns stemming from military service.

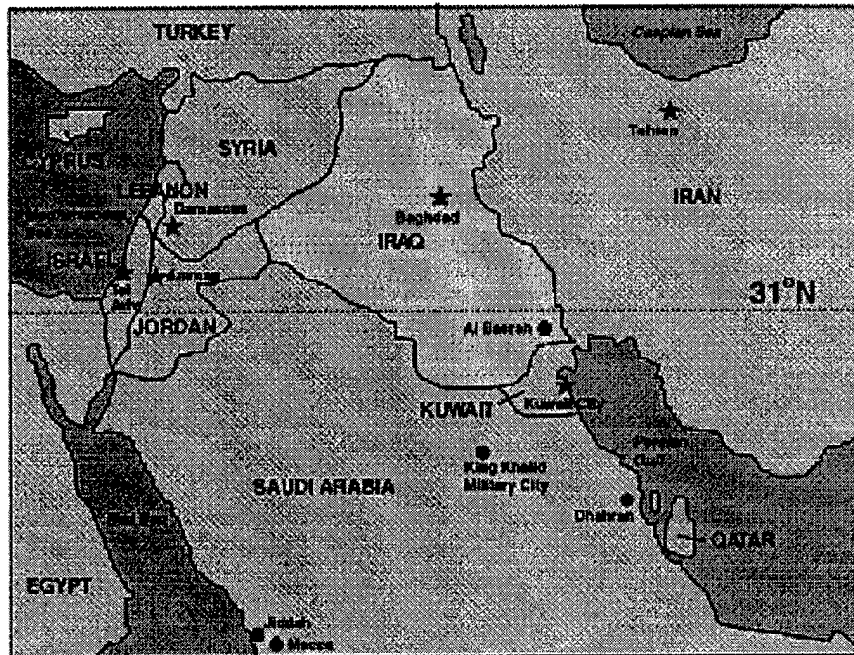
the government continue and intensify efforts to develop stress reduction programs for all troops, with special emphasis on deployed troops.

### **CONCLUSION**

Approximately 697,000 men and women answered the call to serve in Operations Desert Shield/Desert Storm. In many important ways-through medical care, outreach, and research-the Nation has begun to pay its debt to these service members. It is essential, now, to move swiftly toward resolving Gulf War veterans' principal remaining concerns: How many U.S. troops were exposed to chemical warfare agents, and to what degree?

A continued and sustained commitment to a healthy future for Gulf War veterans-for all current and future veterans-is a priority for all Americans. This *Final Report* represents the Committee's contribution to that goal. We have given our full dedication to President Clinton's charge and have appreciated the opportunity to serve Gulf War veterans and their families.

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## **Presidential Advisory Committee on Gulf War Veterans' Illnesses Final Report**

### **Chapter One**

## **INTRODUCTION**

*Caring for veterans is not a national option or a partisan program. It is a national tradition and a national duty. . . . There are thousands of veterans . . . who served their country in the Gulf War and came home to find themselves ill. . . . Just as we relied on these men and women to fight for our country, they must now be able to rely on us to try to determine what happened to them in the Gulf and to help restore them to full health. We will leave no stone unturned.*

President Bill Clinton  
March 6, 1995

Approximately 697,000 men and women served in Operations Desert Shield/Desert Storm ([table 1-1](#)) from August 1990 to June 1991. Americans who fought the Gulf War differed from any force in U.S. history: There was more ethnic diversity, and there were more women, more parents, and more individuals-activated members of the Reserves and National Guard-uprooted from civilian jobs.

During the war, U.S. troops suffered 148 combat deaths and 145 deaths due to disease or accidents; 467 individuals were wounded. Even in the face of these relatively low casualty rates, national leaders anticipated some post-conflict health concerns and initiated programs to address them. The first programs focused on helping veterans readjust to civilian life and cope with the stresses of war. Lessons learned from the Vietnam era prompted officials in the Department of Defense (DOD) and the Department of Veterans Affairs (VA) to provide counseling services-from family therapy to treatment for post-traumatic stress disorder-throughout the war and through the return stateside.

Despite these efforts, some men and women began to experience debilitating illnesses soon after returning from the Gulf. Commonly reported symptoms included fatigue, muscle and joint pain, memory loss, and severe headaches. When several Gulf-deployed members of an Indiana Army National Guard unit reported these symptoms in early 1992, DOD sent in a research team to conduct an epidemiologic study; the team found no evidence of an outbreak of disease. VA contemporaneously established a health registry where Gulf War veterans could report their symptoms. Reports came in, but answers about the nature and cause of the illnesses remained elusive.

### **THE GOVERNMENT'S INITIAL RESPONSE**

Well aware of the problems generated by mishandling Vietnam veterans' health concerns, the government took several actions to address questions about health and Gulf War service, including:

- VA and DOD established medical programs to identify and treat Gulf War veterans' illnesses.
- Congress and the Executive Branch worked together to provide disability compensation for veterans whose illnesses could not be diagnosed.
- VA and DOD joined with the Department of Health and Human Services (DHHS) to conduct research on the prevalence, nature, and possible causes of Gulf War veterans' illnesses.

By early 1995, the clinical evaluation programs had enrolled more than 49,000 veterans and the research portfolio included more than 30 studies. Many medical and scientific experts-from inside and outside the government-had reviewed the government's efforts ([figure 1-1](#)). Still, a substantial number of Gulf War veterans did not have the answers they sought about what kind of illnesses they had, about exposures in the Gulf region that might have made them sick, or about the strength of the country's commitment to its veterans.



To make sure the government was doing all it could as quickly as it could, President Clinton issued Executive Order 12961 on May 26, 1995, to establish the Presidential Advisory Committee on Gulf War Veterans' Illnesses ([appendix A](#)). For the first time, a single body would conduct an independent, open, and comprehensive review of all facets—risks, diagnosis, treatment, and research—related to health issues and Gulf War service.

## THE ADVISORY COMMITTEE

Securing a healthy future for Gulf War veterans is important to all Americans. As First Lady Hillary Rodham Clinton noted at the Committee's first meeting in Washington, DC, on August 14-15, 1995, "We owe them that much, and more." The President charged the Committee to review the full range of government activities relating to Gulf War veterans' illnesses, including:

- research,
- coordinating efforts,
- medical treatment,
- outreach,
- reviews conducted by other governmental and nongovernmental bodies,
- risk factors, and
- chemical and biological weapons ([appendix B](#)).

The Committee—a 12-member panel made up of veterans, scientists, health care professionals, and policy experts ([appendix C](#))—was directed to issue its findings and recommendations to the President through the Secretaries of Defense, Health and Human Services, and Veterans Affairs.

The President made clear his belief that only an open government is a responsive government. Thus, the Committee operated under the Federal Advisory Committee Act, conducting its business in open meetings and providing the opportunity for comment from members of the public at each event. Additionally, the Committee received written submissions for consideration throughout its process.

With the assistance of a full-time staff and consultants ([appendix D](#)), the Committee held ten full Committee meetings and eight focused panel meetings around the country from August 1995 through November 1996 ([appendix E](#)). We heard invited testimony at each meeting, and transcripts of our proceedings and other relevant information were posted on the Committee's home page on the World Wide Web. Staff held in-house expert consultations, received briefings, conducted literature surveys, interviewed veterans, and reviewed government records throughout our tenure.

On February 15, 1996, we delivered our *Interim Report*. In accordance with our mandate, this *Final Report* is being delivered by December 31, 1996.

## PURPOSE AND ORGANIZATION OF THE FINAL REPORT

This document builds on the analyses of the *Interim Report* and reexamines that work in light of information gathered since its publication. Most importantly, the *Final Report* encompasses ground not previously covered—reviewing the full range of the government's efforts to address issues related to Gulf War veterans' illnesses.

This *Final Report* represents the Committee's best judgment on how to improve government programs targeted to Gulf War veterans' health that are, in the main, addressing the concerns of veterans. Our review of outreach, medical and clinical issues, research, and coordination resulted, principally, in findings and recommendations to help the government fine-tune its efforts. The notable exception to our generally positive report comes from our evaluation of the government's efforts to investigate possible exposures of veterans to chemical and biological warfare agents. In this instance we intend our recommendations to be constructive, but the Committee's findings are severe and unequivocal.

The Committee's conclusions appear in three broad chapters. Within each chapter, the Committee outlines the framework that shaped its inquiry; describes background material it uncovered through

testimony, document reviews, and interviews; makes findings based on its investigations; and offers recommendations we believe can improve the government activities under review. The *Executive Summary* distills our findings and recommendations.

In chapter 2, we present our evaluation of the government's outreach, clinical, research, investigative, and coordination efforts. Chapter 2 includes an assessment of the government's response to recommendations from the *Interim Report* and reviews *de novo* issues such as risk communication, access to medical care, the scope of the government's research portfolio, the chemical and biological weapons investigation processes, and the federal government's capacity to respond to veterans' post-conflict health concerns.

Chapter 3 summarizes current data-collected through the clinical programs and from epidemiologic research-on the types of illnesses experienced by Gulf War veterans. Available data are sparse. Generalizable conclusions about the nature and extent of illness will come only from population-based epidemiologic studies that will not be completed until well after this Committee disbands. Already clearly identified, however, are important avenues for research and a continuing need for compassionate care.

The Committee's assessment of possible Gulf War risk factors for service-connected illness appears in chapter 4. We reviewed the limited data regarding the likelihood or extent of exposure to pesticides, chemical and biological warfare agents and the vaccines and drugs used to protect against them, endemic infectious diseases, depleted uranium, oil-well fire smoke and other petroleum products, and psychological and physiological stress. We examined potential health effects of these risk factors in the short- and long-term.

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**Table 1-1-Key Dates During Operations Desert Shield/Desert Storm**

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**1990**

August 2 Iraq invaded Kuwait

August 8 U.S. Air Force planes arrived in Saudi Arabia

August 9 U.S. ground forces arrived in Saudi Arabia

**1991**

January 17 First irretrievable hostile fire

January 20 First oil well fires started in Kuwait

January 27 Coalition forces declared air supremacy

February 19 Majority of oil well fires ignited

February 24 Ground war began

February 25 U.S. troops killed during a SCUD attack in Dhahran

February 28 Offensive operations ceased

June 13 Last U.S. service members who participated in the ground war returned to the United States

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SOURCE: Committee, 1996.

**Figure 1-1 -- Key Organizations on Gulf War Veterans' Illnesses**

1992	August 1992 - Expert Panel on Petroleum Toxicity	Sponsor: DOD
1993	July 1993 - Office of Technology Assessment Workshop on Persian Gulf Health	Sponsor:
	October 1993 Institute of Medicine Committee to Review the Health Consequences of Service During the Persian Gulf War	Sponsor: VA/DOD
	December 1993-June 1994 - Defense Science Board	Sponsor: DOD
1994	January 1994 - Persian Gulf Veterans Coordinating Board*	Sponsor: DOD
	February 1994 - Persian Gulf Expert Scientific Panel	Sponsor: VA
	April 1994 - National Institutes of Health Technology Assessment Workshop Panel	Sponsor: DOD/DHHS/VA/EPA
	May 1994 Dr. Harrison Spencer, Dean, Tulane School of Public Health Independent Counsel	Sponsor: DOD
	June 1994 - Institute of Medicine Committee to Review DOD's Comprehensive Clinical Evaluation Program*	Sponsor: DOD
1995	March 1995 Senior Level Oversight Panel, Persian Gulf Investigation Team, and Declassification Program Sponsor: DOD	Sponsor: DOD
	March 1995 Task Force on Analysis and Declassification of Intelligence Records Sponsor: CIA	Sponsor: CIA
	Presidential Advisory Committee on Gulf War Veterans' Illnesses May 26, 1995	Sponsor:
1996	November 1996 Special Assistant for Gulf War Veterans' Illnesses* Sponsor: DOD	Sponsor: DOD
	November 1996 Special Assistant to the President for Gulf War Veterans Illnesses* Sponsor: National Security Council	Sponsor: National Security Council

\*Operations ongoing

## **Presidential Advisory Committee on Gulf War Veterans' Illnesses Final Report**

### **Chapter Two**

## **THE GOVERNMENT'S RESPONSE**

The President assigned the Committee two principal tasks:

- determine whether the government is doing all it can to discover the causes of Gulf War veterans' illnesses; and
- determine whether the government is delivering quality care to those veterans who are ill.

We initially addressed these questions in our *Interim Report*, which was delivered in February 1996. In the sections of this chapter on outreach, medical and clinical issues, research, and chemical and biological weapons, we include an assessment of how the government has responded to the Committee's *Interim Report* recommendations.

To complete our work, the Committee continued evaluating outreach regarding benefits and services available to Gulf War veterans and also evaluated the departments' risk communication efforts. Committee and staff also conducted a series of site visits to DOD and VA medical facilities, and evaluated the government's ability to respond to reproductive health concerns and the stresses of war. For this *Final Report*, the Committee has assessed the scope of the federally funded research portfolio and the award making process.

We make recommendations for improvement in each of these areas-outreach, medical and clinical issues, and research. Overall, however, the Committee commends the government's response to the range of health-related problems experienced by Gulf War veterans. Lessons were learned from our country's experience with the Vietnam War and the health effects of exposure to Agent Orange. For the most part, the government has acted in good faith and drawn on that experience to significantly improve its handling of Gulf War veterans' concerns.

The Committee is less sanguine about the government's investigation of incidents of possible exposure of U.S. troops to chemical and biological warfare (CBW) agents. Investigatory efforts have been slow and superficial, and no credible attempts to communicate with the public on these investigations have been made. Our most severe criticisms are reserved for this issue. Regrettably, DOD did not act in good faith in this regard.

The most striking feature of our evaluation of the government's response to Gulf War veterans' health issues has been the parallels between the experiences of these veterans and veterans of previous conflicts. We believe the government can do a better job of anticipating and preparing for post-conflict health problems. Thus, in assessing the government's coordination efforts, the Committee recommends an approach that would ensure all of the government's expertise is brought to bear on this issue of critical national concern.

### **OUTREACH**

In our *Interim Report*, the Committee examined some of the outreach programs of DOD and VA. We found they had used a number of progressive techniques-from establishing telephone hotlines for the health care programs that serve veterans to posting declassified documents on the Internet-to educate veterans and other citizens concerned about Gulf War veterans' illnesses. Neither department, however, had adopted performance measures sophisticated enough to evaluate the success of these programs. Our analysis revealed some relatively simple ways for DOD and VA to receive feedback on the utility of various outreach programs and a critical need to present information more clearly to veterans. As a result, our *Interim Report* included the following recommendations:

- Operators at the DOD Medical Registry Hotline, DOD Incident Reporting Line, and VA Helpline should be instructed to ask "How did you find out about this number?" as a method of qualitatively measuring the success of the different methods for publicizing the numbers.
- In the next Comprehensive Clinical Evaluation Program end-of-evaluation questionnaire, which participants answer when the initial evaluation is completed, DOD should include a question about satisfaction with the referral provided by the Persian Gulf Medical Registry Hotline.
- DOD and VA should utilize more refined performance measures to determine how well outreach services are reaching concerned parties. Caller volume data are not adequate.
- To assist the general public in interpreting the declassified intelligence documents on GulfLINK (a DOD site on the World Wide Web), DOD should prepare a user's guide. This guide should explain in general terms the various sources of intelligence information, how they may differ in quality and reliability, and how intelligence analysts compile and evaluate reports from a variety of sources in the field to obtain corroboration before preparing a final assessment. This guide should be featured prominently on the GulfLINK home page.
- In its outreach campaign, VA should forego use of the term "priority care." VA should state clearly that Gulf War veterans are entitled to receive the Persian Gulf Health Registry examination free of charge, including any diagnostic testing found to be medically necessary and counseling regarding findings.
- VA should make its broadcast public service announcements (PSAs) about the toll-free Helpline more explicit. The PSAs should include brief explanations of the purpose of the Helpline and the referral process for the Persian Gulf Health Registry.
- Future conflicts are likely to generate controversial and unexplained health concerns, and DOD and VA should anticipate the need and plan for outreach services and implement them expeditiously.

The following section of the *Final Report* includes the Committee's assessment of the government's response to our *Interim Report* recommendations and includes additional findings and recommendations concerning outreach.

### Departmental Responses

The departments have been responsive to these recommendations. Full implementation will require a long-term commitment that the Committee is not in a position to evaluate.

### Issues New to This Report

To complete our work, the Committee continued the evaluation of outreach to Gulf War veterans concerning benefits and medical services. In addition, we examined the issue of risk communication and whether DOD and VA are communicating effectively with Gulf War veterans about the health risks associated with service in Southwest Asia.

### Outreach Concerning Benefits and Medical Services

For this report, the Committee evaluated outreach efforts (i.e., education and publicity) associated with special government-sponsored readjustment programs, outreach to specific populations of Gulf War veterans, and military broadcasts.

**Outreach component of readjustment programs.** Immediately following the Gulf War, VA's Vet Centers and Persian Gulf Family Support Program (PGFSP) provided services to assist Gulf War veterans and their families in the post-conflict readjustment process. VA's staff for these programs performed a significant amount of outreach about the readjustment services available to active duty and veteran populations. As veterans began to report illnesses and as the government established clinical procedures to evaluate Gulf War veterans, the outreach aspects of Vet Centers and PGFSP continued to educate the public. Both programs quickly mobilized comprehensive outreach efforts and offered a more targeted and directed approach than subsequent DOD or VA efforts, which focused on hotlines and PSAs.

Vet Centers. Congress authorized Vet Centers in 1979. The centers initially offered a range of services to Vietnam veterans, including psychotherapy and counseling, referral and aftercare for substance abuse, crisis intervention for acute symptoms, employment and educational counseling, assistance with upgrade of military discharge, education of community professionals and the public, consultation and input into VA assessments and service decisions at VA Medical Centers (VAMCs), and intensive networking and referral interactions with other community agencies.\* VA's Readjustment Counseling Service (RCS) administers the Vet Center program.

All veterans of conflicts are eligible for Vet Center services. In 1991, RCS directed Vet Center staff to educate themselves about the Gulf War experience by setting up briefings with recent active duty and veteran returnees.

Information gathered via the briefings was presented to an RCS committee, which decided to place programmatic emphasis on meeting the special needs of women veterans and families of veterans. Vet Center staff have seen more than 69,000 Gulf War clients since May 1991. Gulf War clients comprise the largest percentage of the post-Vietnam era group of clients during this period.<sup>297</sup>

Vet Centers operate with considerable autonomy. Each center is staffed by a team leader-typically a social worker or clinical or counseling psychologist-two or three counselors, and an office manager staff. Most centers are nonthreatening spaces located away from the local VAMC (which continues to provide administrative support in the form of supplies, personnel, fiscal processing, and other logistical services). Most staff at Vet Centers have military experience.

Persian Gulf Family Support Program. Congress established an additional resource for readjustment counseling through Public Law 102-405, which directed VA to provide readjustment assistance specifically to Gulf War veterans; the department established PGFSP on October 1, 1992. VA's Social Work Service designed and implemented PGFSP based on recommendations from a task force of officials from VA, DOD, the American Red Cross, and the National Guard. The task force recommended PGFSP include: aggressive community outreach and coordination with National Guard and Reserve Units; case management of clinical services\*\* available at VAMCs, Vet Centers, community agencies, and through contract services not provided by VAMCs; staff training and education components; program evaluation; and national clinical coordination. Acknowledging the essential role families play in the readjustment process, PGFSP architects included marriage and family counseling in the program and provided these services to spouses and children of veterans.<sup>26</sup>

Congress appropriated \$10 million per year for PGFSP for a 2-year period. VA initiated the program at 36 VAMCs in the 26 states with the largest populations of formerly activated National Guard and Reserve troops. The size of the Gulf War veteran population within a VAMC region and empirical projections of the regional need for post-conflict readjustment counseling dictated staffing and funding at each site. A member from each participating VAMC's social work staff was designated PGFSP Coordinator and attended a one-week training session. Training emphasized developing effective working relationships with community agencies, establishing clinics appropriate for the client population, creating outreach goals and strategies, developing assessment and treatment goals, using therapies based on clients' needs, and providing counseling services to veterans and their families. Following training, coordinators integrated PGFSP into their VAMC infrastructures and educated hospital personnel about the evolving policies pertinent to Gulf War veterans.

Initially, the program provided services to assist veterans with readjustment difficulties. In response to concerns about emerging illnesses among Gulf War veterans, coordinators also conducted regional Gulf War illness-related outreach and enrolled clients into VA's Persian Gulf Health Registry (1-800-PGW-VETS). In conducting regional outreach, coordinators briefed National Guard and Reserve units, local veterans service organization (VSO) chapters, state veterans services offices, and grassroots family support groups. Coordinators focused on general information about PGFSP, the illnesses experienced by some Gulf War veterans, and VA's Registry. They also prepared PSAs and gave interviews to local civilian and military media.

Most coordinators appeared to develop close relationships with and personal knowledge of the veterans and active duty community within the region. They tailored appropriate outreach efforts, such as periodic newsletters, brochures distributed throughout the area, and hotline numbers for contacting the local PGFSP. Coordinators also organized "Persian Gulf Health Days" for veterans and the general public, holding them on weekends to maximize attendance. These day-long events often offered educational seminars on illnesses, traumatic stress, and VA benefits, and brought in representatives from VSOs, state and municipal veterans affairs offices, and interested community groups. Participating veterans had the opportunity to enroll in VA's Registry and, at some sites, the Registry examinations were conducted on the weekend as well.

PGFSP coordinators at the 36 sites closely monitored the services provided under the program during its first two years. More than 2,800 outreach briefings were conducted for approximately 70,000 persons, and approximately 22,000 PGFSP outpatient visits were made by veterans and family members nationwide.<sup>166</sup> Funding for the program ended September 30, 1994. Some VAMCs continued to fund aspects of PGFSP, incorporating them into the facility's general budget. Most coordinators, however, returned to their original positions, and after the program ended, spouses and children had to contact Vet Centers to receive free counseling services.

**Transition Assistance Program.** The National Defense Authorization Act of 1991 (Public Law 101-510) authorized DOD, VA, and the Department of Labor (DOL), to provide comprehensive transition assistance for service members separating from active duty. The departments developed a Memorandum of Understanding (MOU) that established the three-day Transition Assistance Program (TAP) and assigned each department responsibilities for its implementation: DOL coordinates implementation; DOD arranges the participation of service members and provides logistical support; and VA presents veterans benefits information. TAP workshops continue to be held periodically at major U.S. military institutions in the United States and overseas, and service members are directed to attend within a 180-day period before separation.

TAP's main objective is to prevent and reduce long-term unemployment problems among veterans by educating them about goal setting, decisionmaking, labor market information, and job search techniques. The interdepartmental MOU, however, also established a high priority for informing veterans about VA benefits. Benefits briefings typically take four hours, during which benefits and application procedures are discussed; there is no standard syllabus for this discussion. It is plausible that briefings include information about DOD and VA clinical programs designed for evaluating Gulf War veterans and their families, but no evidence exists to suggest these programs are mentioned.

**Outreach to women veterans.** More than 40,000 women served in the Kuwaiti Theater of Operations (KTO). Cognizant of the increased role of women in the armed forces and the specific medical needs they could have, Congress authorized-through the Women Veterans Health Program Act of 1992 (Public Law 102-585)-new and expanded services for women veterans. Every VAMC has a Women Veterans Coordinator, who coordinates outreach and clinical services. Vet Centers also are active in providing outreach about specific VA programs for women and in building referral networks for non-VA medical and social services. RCS has a Women Veterans Working Group that has published information on specific health issues related to women veterans and guidance for outreach to this population.<sup>299</sup>

**Outreach to Latino veterans.** New Mexico, Texas, California, Arizona, Florida, and Illinois, as well as the metropolitan areas of Boston, New York City, Chicago, and Milwaukee, have large Latino veteran communities. Vet Centers and VAMCs in these regions typically have a Spanish-speaking staff member who can bridge potential language difficulties and potential cultural barriers to full utilization of the Vet Centers by the Latino veterans community. VA outreach unique to this population includes establishing relations with Latino VSOs, working with Spanish language media to publicize VA programs, and acting as a liaison with other VSOs and VA personnel for assistance in filing disability compensation claims.<sup>298</sup>

## **Military Media**



The American Forces Information Service (AFIS) and its broadcasting arm, the Armed Forces Radio and Television Service (AFRTS), comprise the bulk of DOD's internal information services. AFRTS delivers radio and television programming for service members overseas and aboard ships. AFIS oversees the European and Pacific editions of the *Stars and Stripes* newspapers and the approximately 1,100 military-funded newspapers in the United States and overseas. AFIS also has produced several media products on Gulf War veterans' health issues. Military media have undertaken the following activities related to Gulf War veterans' illnesses:

- Since early 1992 through June 1996, *Stars and Stripes* has printed 118 stories with headlines related to Gulf War veterans' health issues. The coverage appears to be similar to the civilian media, intermittently covering topics as issues evolve. Circulation is 75,000 worldwide, with readership estimates at 175,000.
- Between early 1994 and June 1996, AFRTS has broadcast 19 television and 43 radio spots on Gulf War-related health issues to an audience estimated at one million people stationed overseas and aboard ships. Although a few print stories and broadcast spots communicate how to register for either the DOD or VA clinical programs, most are general news stories on research efforts.
- AFIS also produces an *Internal Information Plan*-a collection of single-page briefs on topics of interest to military personnel, such as voter registration, drug and alcohol abuse, equal opportunity, and military benefits. The *Plan* is distributed to Public Affairs Officers at all units throughout the military, and they are encouraged to disseminate this information to service members. In 1996, a "Persian Gulf Illnesses" brief explaining DOD's Comprehensive Clinical Evaluation Program (CCEP) was added to the *Plan*, but the toll-free hotline for this service was not listed (1-800-796-9699).

## Risk Communication

The Committee first examined the government's outreach programs designed to inform veterans about their benefits. Outreach cannot stop there, however, when veterans have so many questions about the health risks of service in the Gulf. Thus, the Committee also focused attention on another aspect of the government's outreach efforts, namely risk communication.

Risk communication is a multi-step process that involves building a communication plan with specific short- and long-term objectives and using language understandable to lay persons. Risk communication also requires analyzing the affected community to determine effective methods of presenting health information, sustaining the communication process over a period of time to give the community an opportunity to increase its awareness and understanding, and establishing an open process of information exchange between the communicating agency and the affected community. Finally, any strategy must include evaluation of the performance of particular programs.<sup>23,38,48,223,258</sup>

In terms of information requirements, the scenario of Gulf War participants, who were subjected to various potential risk factors during a specific length of time, is analogous to an industrial setting, where workers are exposed to potentially hazardous agents. Additionally, the epidemiologic and clinical studies designed for Gulf War veterans are analogous to studies in which appropriate worker notification measures would be considered. Although a military conflict can be a far more complicated operation than the typical industrial setting, the risk communication experiences of several federal agencies and private institutions provide a suitable framework against which risk communication efforts for Gulf War veterans can be evaluated and compared. Thus, while risk communication in this situation is a challenge, there is a broad theoretical and experience base on which DOD and VA can draw.

Several federal agencies, including the Environmental Protection Agency (EPA) and DHHS's Agency for Toxic Substances and Disease Registry (ATSDR), have developed programs for risk communication with the public about environmental issues and health risks.<sup>30</sup> The National Institute for Occupational Safety and Health (NIOSH) conducts a function of risk communication known as worker notification, in which at-risk industrial workers participating in epidemiologic studies are informed of the results. This step provides the participants probabilistic information regarding the possibility, i.e., risk, of experiencing health effects from exposures.<sup>223</sup> The National Academy of Sciences (a private sector body

that often prepares reports for the government) has published several theoretical and practical guides that emphasize the importance of risk communication in public health.<sup>173,176,177</sup>

**Federal risk communication with Gulf War veterans.** Most DOD and VA outreach efforts concentrate on publicizing the clinical evaluation programs and then referring participants to them. While serving a valuable function, these efforts do not fully educate veterans or sufficiently build their trust that the government's efforts to help them are comprehensive.

In addition, the target population for risk communication related to Gulf War veterans' illnesses extends beyond military service members. Members of the affected community also include family members, civilians who served in the Gulf in support roles, state veterans service officials, and national and local VSOs. Individuals who provide services to the affected community, including social workers and health care providers who come into contact with Gulf War veterans and their families and support groups, are also important risk communication targets.

Some of the departments' outreach efforts provide educational information to veterans. For example, VA publishes the *Persian Gulf Review*, a quarterly newsletter sent to those veterans who have participated in the VA Health Registry or have received other health services from a VAMC. The newsletter carries brief segments of one or two paragraphs about recently released information from reports and studies of Gulf War veterans' illnesses, developments concerning eligibility for medical services and disability compensation regulations, and common questions and answers about how to receive medical care. VA's Persian Gulf Veterans' Illnesses Internet site also provides brief, general information similar in content to the newsletter. Neither the newsletter nor the Internet site, however, provide comprehensive risk communication information about exposures or epidemiologic studies underway.

DOD's Internet site, GulfLINK, attempts to provide more salient information, such as an assessment of health effects from organophosphate exposures and reports of detections of chemical agents during the Gulf War.

However, DOD has been slow to post information, and the tone of some of the posted reports is patronizing and dismissive of veterans' concerns. DOD's growing lack of credibility-attributable largely to chemical warfare (CW) agent exposure investigations (discussed in a following section)-compounds its difficulties with effective risk communication with Gulf War veterans and others. DOD faces a complex challenge in conducting investigatory activities that require contacts with individuals who may face health risks associated with their service in the Gulf. Early efforts, such as the initial Khamisiyah telephone survey, sorely neglected the risk communication element of DOD's responsibilities.

Effective risk communication requires a dialogue-a two-way flow of information, opinions, and perceptions.<sup>258</sup> DOD and VA have not established clear pathways for veterans to provide feedback about clinical programs and/or about concerns regarding exposures; nor have they canvassed the Gulf War veterans' community regarding better methods of communication. It appears the only way in which a veteran could provide feedback would be through contact with the clinical personnel at local VAMCs or military hospitals. This, however, does not appear to be a likely route for transmitting concerns to decisionmakers. VA does conduct periodic interactive video teleconference sessions on Gulf War health topics for clinical and social work staff, but this format is designed for staff education, not as a formal, publicized mechanism of interaction with veterans and other members of the public.

Likewise, the telephone hotlines also are designed for a one-way flow of information. VA and DOD health care hotlines are for referrals only. DOD's Incident Reporting Line (1-800-472-6719) and Khamisiyah investigation telephone survey have been used to collect-not disseminate-information. For example, there often has been no follow-up response from DOD to Incident Line callers about reported incidents, nor has there been adequate disclosure through any existing outreach methods concerning the overall progress of the investigation into CBW agent incidents.

Another opportunity for DOD and VA to interact with members of the target community is in the design and execution of epidemiologic studies. In the *Interim Report*, this Committee found that public

advisory committees might improve communications with veterans who are asked to participate in epidemiologic studies, and we recommended DOD, DHHS, and VA urge their principal investigators to use public advisory committees in epidemiologic studies of Gulf War veterans' health issues. Departmental response to this recommendation has been half-hearted, at best.

DOD and VA need to emphasize feedback procedures in their outreach programs. Creating a dialogue with a disparate veterans population is central to effective risk communication and warrants increased attention from the departments.

**Role of veterans service organizations.** There appears to be a role for VSOs in developing and implementing risk communication strategies for Gulf War veterans, since many VSOs have extensive networks in place throughout the country. VSOs represent veterans in social and legislative matters at the national, state, and local levels. Many VSOs-including the American Legion, Veterans of Foreign Wars, and Vietnam Veterans of America-have been chartered by Congress. VSOs already have an established working relationship with the VA in many areas, including working with Vet Centers on readjustment issues, sitting on the Persian Gulf Expert Scientific Committee, and providing advocates for the disability compensation claims process. Currently, some VSOs are working on behalf of Gulf War veterans, mostly with assistance in the disability compensation claims process. Several VSOs recently have emerged in various regions of the country specifically to serve Gulf War veterans. The interests of many of these groups are represented in Washington, DC, by the National Gulf War Resource Center, which was organized in 1995.

An example of VSOs implementing useful risk communication is the *Self Help Guide for Veterans of the Gulf War*,<sup>178</sup> developed by the National Veterans Legal Services Program (NVLSP) and distributed by the American Legion. The *Guide* provides an overview of the nature of Gulf War veterans' illnesses, explains some health risk factors associated with Gulf War service, and describes eligibility requirements for receiving VA medical benefits. In a different vein, an example of VSOs as a credible resource for veterans is their work in the complicated disability compensation process. Concerned about the 95 percent denial rate for undiagnosed illness claims, the American Legion developed an undiagnosed illnesses application addendum for the VA disability compensation claims process. When completed, the addendum provides a comprehensive description of the veterans' clinical profile and military operational history, which are important factors in the claims process.

The issue of risk communication will only increase in relevancy as studies with specific findings about the nature of Gulf War veterans' illnesses are released. These findings might be unclear to the veterans and, indeed, some conclusions could offer a message some veterans would prefer be different. In such cases, trust, credibility, interaction, and community involvement are key to successful risk communication-but it is not clear whether DOD or VA will have personnel in place to conduct effective risk communication when findings from various reports are ready for dissemination. VA has Persian Gulf Coordinators assigned to each medical center, but these personnel have other responsibilities and typically are more involved with clinical case management.

To date, DOD and VA have not devised a plan with specific objectives for effective health risk communication.<sup>216,217</sup> There are many messages to exchange in a health risk communication process, especially one as complicated as the possible health consequences of service in the Gulf War. A process that adequately addresses risk communication in this area would by necessity involve the following: educating members of the community about the certainties and uncertainties of the health risks of various exposures, using the media as a conduit of information, having frequent and sustained contact with the affected community, and validating the information and the source of information with appropriate external reviews.

### **Findings Regarding Outreach**

Based on its analysis of the government's programs for outreach concerning services available to Gulf War veterans and for communicating with veterans about the risks of Gulf War service, the Committee makes the following findings:

- In their geographic areas, Vet Center staffs have established working relationships with the veterans community, veterans service organizations, local municipal and state veterans liaison offices, in-region Guard and Reserve units, community social services organizations, local VA medical center personnel, and military establishments. These relationships enable Vet Centers to provide education and outreach to local communities about issues and clinical programs concerning Gulf War veterans, and a significant number of Gulf War veterans use their services.
- The outreach initiative of VA's Persian Gulf Family Support Program was an effective method of communicating information about Gulf War veterans illnesses-in particular the established government clinical programs-to veterans, Reservists, National Guard members, and local communities. The program used trained, knowledgeable personnel in the field to establish a communication network with the community and deliver specific information directly to Gulf War veterans.
- Ninety percent of separating active duty service members attend Transition Assistance Program (TAP) workshop briefings conducted jointly by DOD, VA, and DOL. VA benefits briefings during the TAP workshop could be an effective method of outreach about DOD and VA programs for evaluating Gulf War veterans illnesses, yet there is no evidence their clinical programs receive mention.
- Through the initiatives of the Women Veterans Health Programs, VA has implemented a range of efforts to inform women veterans about available health services.
- In regions with significant Latino populations, Vet Centers and VA medical centers deliver bilingual, cross cultural outreach and services.
- While newspaper articles and television and radio broadcasts disseminated by DOD's American Forces Information Service provide adequate media coverage of Gulf War illnesses-related issues, few of the media products perform the outreach functions of publicizing government-sponsored Gulf War veterans clinical programs and methods of referral into them.
- DOD's 1996 *Internal Information Plan-Persian Gulf Illnesses* describes its Comprehensive Clinical Evaluation Program, yet fails to provide the most basic information on how to register for it.
- Effective risk communication is essential to the government's credibility on Gulf War veterans' illnesses, but DOD and VA have not seriously attempted to educate veterans about health effects of service in the Gulf War or to establish a dialogue concerning research programs relevant to veterans' concerns.
- Several federal agencies have developed, tested, and validated techniques for health risk communication that could be adopted by DOD and VA.

The Committee's recommendations for governmental actions based on these findings appear on page 50.

## MEDICAL AND CLINICAL ISSUES

In our *Interim Report*, the Committee focused on medical treatment issues that surfaced during the deployment and demobilization of troops. We found DOD's policies and procedures were not adequate to prevent some service members with preexisting conditions from being deployed or to identify health problems extant at the time of demobilization; we noted these conditions could have contributed to some current health concerns.

The Committee also found that DOD and the Food and Drug Administration (FDA) deliberated carefully before enabling, through rulemaking, DOD to require troops to take pyridostigmine bromide (PB) and botulinum toxoid (BT) vaccine as pretreatments for possible CBW agents without FDA approval of the products for that purpose.<sup>304</sup> We were concerned that FDA had failed, in the five years since the Gulf War, to devise better long-term methods governing military use of drugs and vaccines for CBW defense. We also found DOD's inability to produce records of who received PB or BT indicative of much need for wholesale improvement in the government's performance on medical recordkeeping during military engagements. As a result, our *Interim Report* made the following recommendations:

- DOD should regularly review and update the policies and procedures that govern the pre-, during, and postdeployment medical assessment of the Ready Reserve to ensure they are current and

adequate.

- DOD should establish a quality assurance program to ensure compliance with pre-, during, and postdeployment medical assessment policies.
- Prior to any deployment, DOD should undertake a thorough health assessment of a large sample of troops to enable better postdeployment medical epidemiology. Medical surveillance should be standardized for a core set of tests across all services, including timely postdeployment followup.
- Given that FDA's Interim Final Rule permitting waiver of informed consent for use of unapproved products in a military exigency is still in effect, DOD should develop enhanced orientation and training procedures to alert service personnel they may be required to take drugs or vaccines not fully approved by FDA if a conflict presents a serious threat of chemical and biological warfare.
- If FDA decides to reissue the Interim Final Rule as final, it should first issue a Notice of Proposed Rule Making. Among the areas that specifically should be revisited are: adequacy of disclosure to service personnel; adequacy of recordkeeping; long-term followup of individuals who receive investigational products; review by an institutional review board outside of DOD; and additional procedures to enhance understanding, oversight, and accountability.
- DOD should assign a high priority to dealing with the problem of lost or missing medical records. A computerized central database is important. Specialized databases must be compatible with the central database. Attention should be directed toward developing a mechanism for computerizing medical data (including classified information, if and when it is needed) in the field. DOD and VA should adopt standardized recordkeeping to ensure continuity.

This section of the *Final Report* includes the Committee's assessment of the government's response to our *Interim Report* recommendations and includes additional findings and recommendations concerning medical and clinical issues.

### DOD's Response

DOD has been responsive to Committee recommendations about medical treatment policies governing pre-, during, and postdeployment of U.S. troops. DOD has not been responsive, however, to the Committee's recommendation that prior to any deployment, DOD should undertake a thorough health evaluation of a large sample of troops to enable better postdeployment medical epidemiology.

One of the overriding difficulties of research on Gulf War veterans' illnesses is the absence of baseline data on health and on exposure to environmental hazards. DOD testified it has improved its approach to gathering such data and has incorporated new policies and procedures in its medical surveillance and environmental monitoring programs.<sup>40,213</sup> Although DOD has introduced these techniques in the Bosnia peacekeeping mission, they have not been tested in a large-scale conflict. Laying the groundwork for post-conflict medical surveillance could be perceived by some as a low priority in a war-fighting environment. There is no evidence that DOD has identified a standardized set of tests or physical examination procedures and applied them to a large sample of troops across all services to ensure that medical epidemiology can be conducted in the aftermath of an operation.

With regard to using investigational new drugs, DOD has made the effort in Bosnia to provide information about the risks of tick borne encephalitis (TBE) and the investigational TBE vaccine being administered, with informed consent, to U.S. troops in that region. However, DOD has made no specific response to the Committee's recommendation on educating troops about investigational pharmaceuticals-i.e., given that the Interim Final Rule is still in effect, DOD should develop enhanced orientation and training procedures to alert service personnel they could be required to take investigational drugs or vaccines not fully approved by FDA if a conflict presents a serious threat of exposure to CBW agents.

With respect to our *Interim Report* recommendation concerning medical recordkeeping, the Committee observes that DOD has made progress in working toward improving medical recordkeeping in-theater and stateside. However, increased commitment from DOD's Joint Chiefs of Staff and Commanders in Chief is essential for increasing the priority of this effort.

### FDA's Response

FDA has testified that it is now considering the Interim Final Rule in conjunction with guidelines for CBW agent prophylaxis approval; it is also considering how it should address military and civilian use.<sup>132</sup> The Committee remains concerned, however, about the amount of time FDA is taking to move forward with opening up the Interim Final Rule-which was issued almost six years ago-for public comment.

### Issues New to This Report

To complete its work on medical and clinical issues, the Committee assessed whether Gulf War veterans currently receive access to quality medical care under programs established by the government for their care. We specifically examined the availability of reproductive health care because of the high degree of concern expressed by Gulf War veterans and their families in this regard. Finally, the historically important role of post-conflict stress reactions on the health of veterans<sup>132</sup> led us to give particular scrutiny to this issue.

### Access to Health Care

Beginning with our first meeting in August 1995, the Committee heard frequent public comment about the difficulty of gaining access to health care in VAMCs and, to a lesser degree, DOD medical facilities. Inadequate information, delays in scheduling appointments, insensitive personnel, and inadequate followup topped the list of complaints. The Committee decided a series of site visits and interviews could help inform our deliberations in determining whether problems with access to care persist or largely preceded establishment of VA's Registry and DOD's CCEP. Facilities for site visits were selected to vary geographically and represent initial evaluation sites (Phases I and II) and referral centers. Between November 1995 and February 1996, Committee members and staff visited the following sites:

- VA Medical Center, Washington, DC (Referral Center; Phases I and II)
- VA Medical Center, Durham, NC (Phases I and II)
- VA Medical Center, Houston, TX (Referral Center; Phases I and II)
- VA Medical Center, Indianapolis, IN (Phases I and II)
- Naval Medical Center, San Diego, CA (Referral Center; Phases I and II)
- Walter Reed Army Medical Center, Washington, DC (Specialized Care Center; Phases I and II)
- Eglin Air Force Base, Ft. Walton Beach, FL (Phase I)
- University of Louisville Medical Center, Louisville, KY (CCEP contractor for Fort Knox; Phases I and II)

Site visits included interviews with medical facilities' commanders or chiefs of staff, Registry or CCEP coordinators, medical and nonmedical staff assigned to the program, and veterans undergoing evaluation. Committee members and staff also took walking tours of dedicated facilities and reviewed randomly selected medical records of Gulf War veterans.

**Clinical evaluation programs.** In August 1992, VA established its Registry for veterans who had returned to civilian life. DOD established the CCEP in June 1994 for Gulf War veterans remaining on active duty. These clinical programs are available, free of charge, to any Gulf War veteran. Both the Registry and CCEP are treatment programs, not research protocols, but the data have been used to generate research hypotheses.

VA and DOD maintain databases for their clinical care programs. The databases for the Registry and CCEP can generate information useful for patient care-both for diagnosis and for risk communication.

**Quality of care.** The VA Registry originally consisted of a medical history, a thorough physical examination, and basic laboratory tests. If indicated, participants received specialty consultations as Phase II of the evaluation. While the Phase I and Phase II examinations essentially were equivalent to a good internal medicine evaluation, initially no uniform protocol existed for the assessment of participants in the Registry. As the program developed, VA established requirements for certain specialty examinations for all participants and standard questions regarding possible exposures while in

the Gulf. By early 1994, a uniform assessment protocol, which is in use today, was in place systemwide. As of October 1996, approximately 62,000 Gulf War veterans had completed physical examinations in VA's Registry program. The most frequently cited symptoms, which have remained consistent over time, include fatigue, headache, skin rash, muscle and joint pains, and memory loss. The majority of participants receive a diagnosis, but approximately 20 percent of veterans who describe symptoms during the physical examination(s) complete the Phase I and/or Phase II examinations without receiving a diagnosis.

DOD uses the same examination protocol for its CCEP.\*\*\* Initially, any CCEP participant who wanted a Phase II evaluation was given one without a specific referral from his or her physician. DOD modified this policy in January 1995 and now requires a physician referral for Phase II. As of October 1996, approximately 34,000 individuals had requested physical examinations in the CCEP. DOD has published information derived from more than 18,000 CCEP examinations,<sup>277</sup> and the findings are similar to those for VA's Registry. The most frequently cited symptoms have been fatigue, headache, skin rash, joint pain, and memory loss. All CCEP participants receive a diagnosis, but approximately 18 percent of the primary diagnoses fall into the category "ill-defined symptoms and signs," with no specified cause.

VA designated medical centers in Washington, DC, Houston, TX, Los Angeles, CA, and Birmingham, AL, as Referral Centers for evaluating veterans who have unexplained illnesses after the Phase I and II examinations. DOD established a Specialized Care Center at Walter Reed Army Medical Center for the evaluation, treatment, and rehabilitation of Gulf War service members with chronic debilitating symptoms.

**Appointment scheduling.** VA offers the Phase I examination at any VA medical facility; Phase II examinations are performed at any secondary or tertiary care facility. Phase I evaluations through the CCEP can be done at any military treatment facility. DOD's Phase II evaluations are conducted at one of the 14 tertiary care medical facilities (one for each of the 13 geographic regions except region 6, which has two) with the required specialty staff.

When VA's Registry began in 1992, veterans often encountered significant delays throughout the system in scheduling appointments-chiefly because of the large number of veterans requesting examination, the newness of the program, and the need to reassign space and personnel within facilities. Experience gained over time, the development of streamlined procedures, and the decreasing rate of veterans entering the Registry largely have eliminated major delays in scheduling an initial examination. Delays-usually less than 30 days-can occur in scheduling Phase II evaluations depending on the availability of specialists.<sup>4</sup> Evaluations at one of VA's four Referral Centers entail administrative delays associated with medical records preparation and consultations with referring physicians. Referral Centers follow a more rigorous protocol requiring a greater commitment of time and specialty resources and limits the number of participants at any one time. Delays of three months or more are not uncommon.

The Committee heard fewer complaints about initial appointment scheduling in the CCEP program and found that delays in scheduling

Phase II referrals seldom exceed two weeks. The Specialized Care Center at Walter Reed, a rigorous 30-day program, requires advance scheduling and consultation, but at the time of our visit we heard of no delays.

**Personnel and space.** By the time Committee members and staff initiated our site visits in November 1995, all facilities had a designated Gulf War Veterans Program coordinator and support staff who were responsible for scheduling and conducting the evaluations. Committee and staff interviewed these individuals and found them knowledgeable about the Registry or CCEP programs and their individual responsibilities. Staffing at the facilities we visited is currently sufficient to conduct Phase I and Phase II evaluations, although the variability of available specialists to conduct portions of the Phase II evaluation causes some delays in a few of the facilities visited.



The large numbers of service members who registered in the CCEP initially threatened to overwhelm the resources of the Internal Medicine Department at Fort Knox. A significant backlog of participants awaiting Phase I evaluation existed in February 1995, when DOD mandated that all requested workups nationally would be completed by April 22, 1995. Because Fort Knox had only three internists at the time, CCEP registrants consumed all of their clinic time. In response, two physicians from Wright-Patterson Air Force Base were detailed to Fort Knox to assist with the evaluations. Contract arrangements also were made with the University of Louisville to conduct Phase I evaluations from Fort Knox beginning July 26, 1995. Participants requiring Phase II evaluations are still referred to the U.S. Air Force Hospital at Wright-Patterson Air Force Base, Dayton, OH, but Phase II evaluations now also are conducted at the University of Louisville.

The Fort Knox example of clinic overload was the most extreme example of clinical disruption at facilities visited by the Committee. Eligible beneficiaries who were not on active duty, other than Gulf War veterans, who requested appointments at the Fort Knox Internal Medicine Clinic in the spring of 1995 were referred to civilian care under DOD's Civilian Health and Medical Program of the Uniformed Services (CHAMPUS). All other facilities we visited maintained they had extended hours and worked harder to avoid interfering with the usual hospital routine. In our conversations with clinic and program staff, they noted there had been some disruption in the early part of both clinical care programs, but that the problems had not been severe. The most frequently mentioned effect was the pressure on clinical and program staff to complete the evaluations in a timely manner-particularly at the DOD facilities during January to May 1995.

Most facilities did not designate a separate clinic space for Phase I evaluations, seeking to mainstream participants as much as possible and reduce the possibility of symptom sharing. Some facilities (e.g., VAMC, Durham, NC), have set aside specific clinic hours for the Gulf War evaluations and report no evidence of symptom sharing among their group of veterans. With the significant reduction in numbers of Gulf War veterans seeking evaluation, all clinical spaces we visited are more than adequate to handle current demand. As was noted earlier, however, the extent to which this remains true is unclear, given recent heightened media attention to Gulf War illnesses.

**Staff education.** In contrast to the extensive knowledge of staff assigned directly to Gulf War-related programs, the knowledge level of staff not specifically assigned to the Registry or CCEP at both VA and DOD medical facilities was problematic. For example, the existence of the CCEP was largely unknown among staff at the VA facilities we visited. Moreover, it was astonishing in one instance to find that a physician treating Gulf War veterans in his VA post-traumatic stress disorder (PTSD) research was unaware of the VA Registry. There have been scattered Continuing Medical Education (CME) programs for DOD and VA medical facility staff about the government's Gulf War programs, but these are intermittent, usually limited to a single department, and not well attended.

At the time of the Committee's site visits, some staff at the VA medical facilities complained they were receiving less information about the program from VA Central Office than they felt they needed. While recognizing the educational outreach concerning the Registry program undertaken by the Central Office, they wanted more information about results of the Registry evaluations and about research being undertaken. Staff at DOD's facilities expressed general satisfaction with the feedback they received.

**Staff attitudes.** The Committee heard public comment at each meeting citing insensitive attitudes on the part of staff at both DOD and VA medical facilities. Frequently, these reports by veterans and their families centered on a dismissive or cynical approach to the veterans' problems-i.e., the message received was that problems were "not real" or "all in your head." Veterans who sought care after the Gulf War but before the establishment of the Registry and CCEP appeared to suffer most from this treatment.

In our interviews with staff at the eight medical facilities, we encountered a range of views about the problems being experienced and reported by Gulf War veterans. Some VA and DOD staff members expressed the belief that the thorough, structured evaluations in the Registry and CCEP were overkill and were exacerbating any problems that existed through the reinforcement of a sick role. Others felt constrained by the rigidity of the evaluation protocol-that it did not allow for flexibility of clinical



judgment-and felt this was "not the way I would practice medicine." No VA or DOD staff members interviewed stated they believed that these veterans were not actually ill.

Patient satisfaction surveys carried out at several of these facilities find a greater than 80 percent approval rate by all patients, including Gulf War veterans.

**Adequacy of medical records.** Medical records of Registry and CCEP participants at each facility are maintained separately from other patient records, and there is a final, common pathway for determining when the records are complete and ready to be certified by a physician's signature. When completed, patient data are reported to either VA Central Office or DOD Health Affairs.

Committee staff reviewed a ten percent sample of randomly selected medical records of Gulf War veterans at each facility visited. Records were reviewed for completeness, adherence to protocol and, particularly, documentation of diagnoses by specialty consultation and/or laboratory reports.

In its reviews, Committee staff found only minor deviations from completeness and adherence to protocol. In each instance where Committee staff noted missing documentation for a discharge diagnosis, facility staff was able to locate the necessary documentation. It appears that, overall, medical records for these veterans are complete.

**Follow-up treatment.** After completing a Registry or CCEP examination, Gulf War veterans are, in most instances, returned to their local medical facility for follow-up care. Despite the general medical adequacy of the VA and DOD evaluation programs, follow-up treatment-particularly where mental health visits are involved-are problematic. Staffing constraints often result in long delays in scheduling appointments in some specialties. Psychiatric staffing is particularly overloaded at some sites.

Many Registry and CCEP participants are receiving follow-up care from a number of physicians, both federal and private sector. No single case manager is guiding their care. The absence of a case manager can lead to confusion and, in some cases, over medication of patients.

Follow-up treatment of active duty veterans also is made more difficult by command resistance to granting the necessary time off to maintain an adequate treatment program. This is true for all chronic illnesses, but especially so for psychological diagnoses.

## **Reproductive Health Services**

The birth of a child with a disabling, disfiguring, or lethal condition is devastating to the parents and family of that child. Likewise, the inability to produce a wanted child is usually unexpected and almost always anguishing. Most people want to know why this has happened to them and their family. Understanding what caused, or at least did not cause, the problem can often bring relief.

**Care provided to active duty service members.** When a couple experiencing infertility, a woman in a high risk pregnancy, or an infant with a birth defect enters the military health care system, a comprehensive range of services-from primary to tertiary care-are available. Beneficiaries who experience fertility problems can use their benefits to obtain a variety of reproductive health services, including infertility testing and treatment. A

child with special health needs receives a full range of medical and related health care benefits to the full extent of his or her disability. In addition, a child with a disability and incapable of self-support remains eligible for care in the military's medical services system as a family member of an active duty member or retiree, even after the age of majority.<sup>256</sup>

**Care provided to veterans who have separated from service.** Reproductive-related medical care and counseling for individuals no longer on active duty stands in stark contrast to coverage for active duty service members. With the exception of children with spina bifida born to in-country Vietnam veterans, VA currently lacks the authority to provide benefits or services on the basis of adverse health effects in children-even if the effects are shown to result from their parents' service experience. Evaluation and

treatment for infertility of veterans is limited to a small number of situations in which the cause of the infertility could have been detected and treated while on active duty (e.g., diabetes in women or service-related spinal cord injury in men). In general, obstetrical services are not offered to female veterans through the VA medical system-except for care relating to a pregnancy that is complicated or in which the risks of complication are increased by a service-connected condition. VA has no policies in place to systematically address the concerns of Gulf War veterans regarding reproductive health.

### **Prevention of Combat-related Stress Reactions**

Building on research on veterans of Korea, Vietnam, and the Gulf, DOD has undertaken an ambitious program to proactively address combat-related stress. The U.S. Army, through the Department of Military Psychiatry, Walter Reed Army Institute of Research, has instituted a Human Dimensions Research Program. One important observation has been that strong leadership and unit cohesion are firmly associated with reduced severity of stress reactions. U.S. Army doctrine embraces this finding and emphasizes it in its field manuals.

Combat Stress Control Detachments have been established (six in the Active Army and nine in the Reserve), each consisting of a psychiatrist, psychologist, social worker, psychiatric nurse, clinical nurse specialist, occupational therapist, and two enlisted technicians. These detachments provide predeployment briefings that address all known health hazards, including stress, that individuals might face during the deployment. During deployment, members of the detachments are instructed to be highly visible to the commanders and troops. One of these detachments has been deployed to Bosnia.

Combat Stress Control Detachments provide briefings for units newly arrived, provide special training in stress management techniques and, most important, they conduct unit survey interviews throughout the deployment. Unit interviews are a systematic tool for gathering information from the troops and then reporting to the command what is troubling the troops and how well leadership is functioning. When critical events occur, the trained individuals in the detachments debrief personnel directly involved, provide consultation to the leaders and chaplains, and provide any special education that could be needed. At the end of a deployment, all units, including those in which no critical events occurred, receive an end-of-tour debriefing by the Combat Stress Control Detachment. Those units exposed to particularly critical events receive special attention to ensure that unit members have a chance to talk through events and reach appropriate closure prior to returning home.

Follow-up plans for the Bosnia deployment include studies that will take place six months after veterans return. Plans also are under discussion to continue to follow the same individuals, with appropriate informed consent, over the long term.

Tertiary prevention programs, such as Vet Centers within the VA medical system, also can help minimize stress-related conditions before they become too severe. As noted earlier in this chapter, Vet Centers were established after the Vietnam War to provide support for Vietnam veterans with PTSD and other mental health concerns. There are 205 centers located around the United States, and since 1991, more than 66,000 Gulf War veterans in over 210,000 visits have availed themselves of these centers.<sup>8</sup>

### **Findings Regarding Medical and Clinical Issues**

Based on the government's response to the recommendations in the Committee's *Interim Report* and additional interviews, site visits, briefings, and testimony, the Committee makes the following findings regarding medical and clinical issues:

- DOD has not been responsive to the Committee's recommendation that prior to any deployment, DOD should undertake a thorough health evaluation, including a core set of diagnostics, of a large sample of troops to enable better postdeployment medical epidemiology along with timely postdeployment followup.
- FDA is moving toward soliciting public comment on alternatives to the Interim Final Rule related to permitting a waiver of informed consent for use of investigational products during military exigencies. The Committee remains seriously concerned about the amount of time-currently

- approaching six years-FDA is taking to open the process to public comment.
- DOD has not been responsive to the Committee's recommendation that it should routinely inform recruits and troops, through orientation and training procedures, about the possible use of investigational drugs or vaccines for chemical and biological warfare agent purposes. DOD's lack of response in this highly sensitive area contributes to the perception of many that U.S.
  - troops were inappropriately subjected to investigational drugs or vaccines during the Gulf War.
  - DOD has made progress in improving medical recordkeeping in-theater and stateside, but increased and sustained commitment from DOD's Joint Chiefs of Staff and Commanders in Chief will be necessary for current prototypes and plans to be fully and successfully integrated and implemented.
  - Clinical staff not directly involved in VA's Registry and DOD's CCEP are not well informed about the programs.
  - Follow-up treatment, particularly when mental health visits are involved, is problematic within both VA and DOD. Staffing constraints occasion long delays in scheduling appointments. Commanders are sometimes resistant to making sufficient time off available for active duty veterans to maintain an adequate treatment program.
  - Reproductive health care benefits available to active duty service members and their families through the Military Health Services System are comprehensive and the standard of care.
  - Reproductive health concerns are addressed on a case-by-case basis within DOD, and VA has extremely limited authority to treat such concerns at all. Neither DOD nor VA have widespread or systematic policies in place to address the concerns and questions of Gulf War veterans concerning reproductive health.
  - DOD and VA have implemented innovative programs to help veterans cope with combat-related stress.

The Committee's recommendations for governmental actions based on these appear findings on page 52 of the printed version of the *Final Report*.

## RESEARCH

In our *Interim Report*, the Committee found most of the major epidemiologic studies sponsored by DOD, VA, and DHHS to be well designed and appropriate to determine if Gulf War veterans have mortality, symptoms, or diseases that could be attributable to service in the Gulf War. We were concerned, however, that inadequate response to scientific peer review, disregard for the importance of allocating scarce research dollars to the best designed studies, and inattention to the need to communicate effectively with veteran participants were undermining the effectiveness of the government's research efforts. Finally, we found that the lack of data about exposure to various risk factors was hampering ongoing research. The Committee's *Interim Report* included the following recommendations based on our preliminary analysis of the government's research programs:

- All epidemiologic studies aimed at Gulf War veterans' health issues should incorporate external scientific review and ongoing interaction with appropriate outside experts throughout the study process, from study design through analysis of results.
- The Persian Gulf Veterans Coordinating Board should play an active role in allocating the limited resources available for research on Gulf War veterans' illnesses. The Research Working Group of the Coordinating Board should monitor the findings and recommendations of scientific peer review committees. If scientific reviews draw into question the usefulness of particular studies to the overall research strategy, the Research Working Group should, via the Coordinating Board, recommend appropriate actions to the Secretaries of the three departments involved.
- DOD, DHHS, and VA should recommend their principal investigators use public advisory committees in designing and executing epidemiologic studies of Gulf War veterans' illnesses.
- For those questions that are common to different epidemiologic surveys, coordination between principal investigators and survey design experts should take place to arrive at common wording. The Persian Gulf Veterans Coordinating Board's Research Working Group should take responsibility for this coordination.
- The Persian Gulf Registry of Unit Locations should be made available to qualified government and private researchers as quickly as possible, within the constraints of confidentiality.

- DOD should make reasonable and practical efforts to collect and record better troop exposure data during future conflicts and to make those data available as quickly as possible to health care researchers.

The following section of the *Final Report* includes the Committee's assessment of the government's response to our *Interim Report* recommendations and includes additional findings and recommendations concerning research.

## **Departmental Responses**

The government has been responsive to these recommendations in general, but the Committee notes continuing problems in two areas: the use of public advisory panels for epidemiologic studies and the utility of the Persian Gulf Registry of Unit Locations.

**Public advisory panels.** While VA and DOD have encouraged their principal investigators to convene and consult scientific advisory committees, they have not taken serious steps to encourage the formation and use of public advisory committees. Although public advisory committees will be recommended for epidemiologic studies recently funded by DOD and VA, their use is given low priority by program administrators. The Committee believes this practice is unfortunate because, as is evidenced by the experience of the Centers for Disease Control and Prevention (CDC), public advisory committees can greatly facilitate incorporation of veterans' concerns into study design, dissemination of results, and risk communication.

**Persian Gulf Registry of Unit Locations.** DOD has made its congressionally mandated Persian Gulf Registry of Unit Locations available to govern

ment and private researchers, but the database lacks the precision and detail necessary to be an effective tool in the investigation of exposure incidents. More to the point, the unit locator database has failed in its application to the single CW agent incident investigated by DOD in any detail to date-i.e., Bunker 73 and the pit at Khamisiyah.

In its Khamisiyah investigation, the Persian Gulf Veterans' Illnesses Investigation Team (PGIT) has not relied on reports provided from the database because the assumption on which the database is premised-that individuals remain with their units-was the exception rather than the rule in the theater of operations. Instead, PGIT went to the operational records and has engaged in a series of interviews to try to piece together a more accurate picture of troop locations. PGIT found that, in the field, individuals performed duties while assigned to discrete groups that might or might not be represented by one of the database's unit identification codes. In addition, records of unit locations, which still are maintained manually, were sometimes incomplete and/or inaccurate. For these reasons, the Committee concludes the unit locator has not proved to be a valuable tool for investigating exposure incidents. The effort has been no more successful than the effort to compile similar information following the Vietnam War to examine possible exposures to Agent Orange. Regrettably, DOD raised expectations about the potential utility of the database far beyond reason, given the data available to developers of the computer database. Better data-whether acquired through rigorously enforced manual methods or new technologies such as devices that interact with the Global Positioning Satellite system-should receive higher priority from DOD.

## **Issues New to This Report**

To complete its evaluation of federally funded research on Gulf War veterans' illnesses, the Committee assessed whether the government's research portfolio is well managed and whether federally funded research addresses an appropriate range of questions relevant to Gulf War veterans' illnesses.

## **Management of the Federally Funded Research Portfolio**

The Committee focused on four areas related to the government's management of federally funded research in Gulf War veterans' illnesses: coordination, research centers, prioritization, and external

review.

**Coordination.** The Persian Gulf Veterans Coordinating Board (Coordinating Board) manages the government's Gulf War veterans' health research. Established in January 1994, the interagency Coordinating Board is comprised of the Secretaries of Defense, Health and Human Services, and Veterans Affairs, and its Research Working Group (RWG) has primary responsibility for research related to possible health consequences of Gulf War service. The RWG's tasks include coordinating studies to avoid unnecessary duplication, ensuring a focus on high priority research, assessing the status and direction of federally funded research, identifying possible gaps in understanding

Gulf War veterans' health issues, recommending future research directions, and generating periodic reports to Congress. Oversight of individual projects within the government's portfolio rests within the funding agency. Each department has its own established funding and management procedures for its intra- and extramural research programs.

DOD and VA have historical roles in research on the health of active duty service members and veterans, and they take the lead in the RWG partnership. DHHS has historical strengths in public health (e.g., CDC) that are brought to bear in this effort. However, except for the National Institute of Environmental Health Sciences, DHHS's many basic biomedical research intramural activities and extramural projects that could contribute substantial expertise to Gulf War health issues are peripherally involved in RWG's activities, if at all.

**Research centers.** The government has developed some innovative approaches to address Gulf War veterans' health research. For example, in October 1994 it launched three Environmental Hazards Centers in Portland, OR, East Orange, NJ, and Boston, MA. At the outset, the goal was to bring together teams of highly qualified researchers with relevant expertise in veterans' health issues. The centers are joint VA-university endeavors-each funded at approximately \$500,000 per year for five years-and they support interdisciplinary collaborations and interactions between VA and academic scientists.

Testimony before the Committee and staff site visits indicate each of the centers brings a different array of expertise to the broad set of questions relevant to Gulf War veterans' illnesses. To date, the centers have produced some well-designed studies. Moreover, the range and depth of research at the centers suggests these studies will provide useful contributions to understanding Gulf War-specific health concerns, as well as those that could arise with future conflicts.

The possibility that reproductive health problems and birth defects might be tied to service in the Gulf War is of special concern to many veterans and their families. VA solicited applications in May 1996 to establish a research center for epidemiologic, clinical, and basic science studies of environmental hazards and their effects on reproductive and developmental outcomes. In November 1996, the VAMC in Louisville, KY was selected as the site for this multidisciplinary center. The center may collaborate with federal and state agencies that collect birth outcome data and that have experience with relevant chemical exposures. The center is not specific to reproductive issues related to Gulf War veterans, but has the broader mission of analyzing reproductive health research for all veterans.

**Prioritization.** In addition to developing the center-based approach, RWG also established priorities for federally funded research on Gulf War veterans' illnesses. Research priorities were published first in August 1995.<sup>294</sup> These evolved over the next few months, and in response to questions from the Committee in May 1996, the RWG identified and ranked priority research areas.<sup>149</sup> In order of priority, these were:

- reproductive health, including male contribution to adverse reproductive health outcomes;
- mortality follow-up studies;
- stress;
- illnesses in non-U.S. coalition forces and indigenous populations;
- toxicology of pesticides, CW agents, and PB (alone and in combination with other factors);
- toxicology of depleted uranium (DU), solvents, and fuels; and

- infectious diseases, especially leishmaniasis and BW agents.

The Committee commends the effort to set priorities and notes these priorities were applied to the most recent round of the government's research awards. We have identified a more narrow range of priorities for research on Gulf War veterans' health concerns. Specifically, the Committee views the principal uncertainties about Gulf War veterans' illnesses as: the long-term health effects from low-level exposure to CW nerve agents, the long-term health effects from stress, the long-term health effects from exposure to known carcinogenic and mutagenic compounds (such as mustard agent), and the long-term health effects of interactions between PB and other agents. We note that RWG's new priorities, published in November 1996, emphasize clinical investigations of service members who may have been exposed to CW agents.<sup>295</sup> The Committee agrees with the RWG that research on other (former) priority areas could be important for future conflicts.

**External review.** The departments have incorporated external scientific merit review into their research selection processes. Proposals for funding through DOD's fiscal year 1995 Broad Agency Announcement (BAA) were reviewed for scientific merit and relevancy by the American Institute of Biological Sciences.

To maximize the validity and interpretability of study findings, and as recommended in the Committee's *Interim Report*, external scientific review has been incorporated for most studies. External scientific review for smaller studies supported by indirect cost accounts is more variable.

Each agency of the RWG has its own standing advisory committees charged with overseeing research generally, including VA's Persian Gulf Expert Scientific Committee, the Armed Forces Epidemiology Board, the Defense Science Board (DSB), and study groups at the National Institutes of Health (NIH). None of these groups, however, has interagency appointments and/or responsibilities. Moreover, none is charged specifically with overseeing post-conflict health research.

### Content of the Research Portfolio

The U.S. government funds a broad range of research in Gulf War veterans' illnesses. Figure 2-1 illustrates the distribution (by numbers of studies) of the federal research commitment specifically dedicated to Gulf War veterans' health. These studies are not equivalent in terms of cost, number of participants, or likely contribution to understanding Gulf War veterans' health. Appendix F categorizes the research portfolio by type of study and lists the health issue(s) under investigation, research institution, funding agency, anticipated completion date, and publications to date.<sup>295</sup>

**Epidemiologic studies.** As of Fall 1996, the federal government has funded 23 epidemiologic studies (22 percent of the total number of studies). These projects are intended to evaluate the occurrence of disease in Gulf War veterans and the factors that influence their occurrence, severity, and outcome. Individual studies examine different groups of veterans and different diseases and health outcomes. For example, subgroups include women veterans, servicemen and women from countries other than the United States, veterans who have enrolled in the VA Registry, veterans who now live in specific states, veterans who have been hospitalized, and specific veteran groups such as the Seabees. Health outcomes under investigation include cancer rates; rates of infertility, birth defects, and miscarriages; causes of death since return from the Gulf War; general well-being; current health status; and operational case definitions that have been empirically developed for specific subgroups of veterans.

Most of the major, federally funded epidemiologic studies were reviewed in the Committee's *Interim Report*. Upon completion, this epidemiologic research aims to answer some fundamental questions about the health of Gulf War veterans: Are Gulf War veterans as a population exhibiting specific symptoms, diseases, and death at a greater rate than seen in veterans who did not serve in the Gulf War? If so, what are the specific diseases or causes of death that are increased? Results from this epidemiologic research will be crucial for identifying future research needs, as well as which risk factors should receive additional research attention.

**Gulf War risk factors and health outcomes.** Health outcomes for Gulf War veterans under investigation in Fall 1996 included reproductive health; diarrhea and gastrointestinal disorders; irritable bowel-like disorders; immunological function; respiratory function; fibromyalgia; musculoskeletal symptoms; sensitivity to chemicals; fatigue, stress, mental health, and neurophysiologic and neuropsychologic status (including PTSD and Chronic Fatigue Syndrome (CFS)). Many of the projects on specific health outcomes also are based on epidemiologic approaches.

Currently, stress is the risk factor funded for the greatest fraction of total studies-32 studies (30 percent). Other federally funded research investigating possible health effects of specific Gulf War risk factors-often involving animal models-include projects assessing mustard agent; organophosphorus (OP) nerve agents; DU; infectious disease, especially leishmaniasis; oil-well fire smoke; leaded fuels; and PB in combination with insecticides and other agents (figure 2-1).

As summarized in figure 2-1 and appendix F, the government's research portfolio on possible health consequences related to Gulf War service has directed significant effort toward addressing uncertainties specific to Gulf War veterans. Other portions of the research portfolio, however, can only be justified as anticipating health issues in future conflicts-i.e., the general health consequences of military service.

**Low-level effects of chemical warfare agent exposure.** Newly released information has affected the relative importance of certain risk factors. Prior to June 1996, DOD ignored calls from its own DSB<sup>279</sup> and others for research on the possible long-term health consequences of low-level exposure to CW agents. DOD's intransigence in refusing to fund such research until Summer 1996 has done veterans and the public a disservice.

The recent revelations about possible exposure of some U.S. service personnel to low levels of CW agents during the destruction of Iraqi chemical munitions at Khamisiyah have elevated this research issue, however, and altered DOD's posture toward funding such projects. As of November 1996, the RWG was developing the government's approach to fund research in this area. The RWG will need to consult with experts in and out of government to ensure that difficulties (e.g., institutional barriers, inadequate access to expertise, and lack of a clear management strategy) do not impede progress in this important research area.

DOD has committed \$5 million from fiscal year 1996 funds for collaborative DOD/VA research-as identified by the RWG-on possible low-level effects from CW agents. Projects initially slated to receive funds (\$2.5 million) include three previously unfunded proposals based on animal model experiments. Current plans are to identify and fund additional clinical and epidemiologic studies on this topic with the remaining \$2.5 million. DOD's recently announced plans to increase funding for all research on Gulf War veterans' illnesses could result in additional funds for study of low-level exposures to CW agents. In early December 1996, DOD issued a solicitation for proposals for such research.

## Findings Regarding Research

Based on the government's response to the recommendations in the Committee's *Interim Report*, a review of the federally funded research portfolio for Gulf War veterans' health, and a parallel, but independent, review of potential health risk factors that could be associated with service in the Gulf War (see chapter 4), we make the following findings:

- DOD and VA have not taken serious steps to encourage their principal investigators to convene and use public advisory committees for its Gulf War veterans' epidemiologic health research.
- DOD's Persian Gulf Registry of Unit Locations lacks the precision and detail necessary to be an effective tool for the investigation of exposure incidents. The effort has been no more successful than the effort to compile similar information following the Vietnam War to examine possible exposures to Agent Orange.
- Overall, the government's current research portfolio on Gulf War veterans' illnesses is appropriately weighted toward epi
- demiologic studies and studies on stress-related disorders that are more likely to improve our understanding of Gulf War veterans' illnesses. For the most part, the government's prioritization



process has worked.

- Research on Gulf War veterans' illnesses is treated, appropriately, as a subset of the government's broader research portfolio on the health consequences of military service. Any new research funds should be directed toward the principal uncertainties, which are: long-term health effects from stress; long-term health effects from low-level exposure to chemical weapons; long-term health effects from exposure to known carcinogenic and mutagenic compounds, such as mustard agent; and long-term health effects of interactions between pyridostigmine bromide and other agents.
- Stress is not well understood in terms of diagnoses, physiological sequelae, and effective prevention and treatment strategies; yet it is likely to be an important contributing factor to illnesses currently reported by Gulf War veterans. Additional attention to basic and applied research on stress-related disorders across the entire federally funded biomedical research portfolio would benefit DOD's and VA's capabilities to manage combat stress and its effects.
- The efforts of the Coordinating Board's Research Working Group would benefit from the active participation of additional representatives from other federal agencies with relevant expertise, such as the National Institutes of Health and the Agency for Toxic Substances and Disease Registry.
- VA's November 1996 establishment of a new Environmental Hazards Center focused on reproductive health and developmental outcomes from environmental exposures is an important step forward in developing policies for the treatment of veterans and addressing their concerns.

The Committee's recommendations for governmental actions based on these findings appear on page 53 of the printed version of the *Final Report*.

## CHEMICAL AND BIOLOGICAL WEAPONS

At the time the Committee issued its *Interim Report*, we were still in the initial stages of reviewing information gathered by the United Nations Special Commission on Iraq (UNSCOM) since the end of the Gulf War about Iraq's advanced CBW capabilities. UNSCOM's work, which continues today, has played a critical role in discovering the extent of possible exposures of U.S. troops to CBW agents during the Gulf War.<sup>262</sup>

In our *Interim Report*, we found the decisions of DOD and the Central Intelligence Agency (CIA) to reopen their investigations of chemical and biological weapons in the Gulf War to be constructive steps and urged DOD and CIA to draw fully on their resources to answer some of the

war's most controversial questions. We stated our intention to monitor their progress carefully. Additionally, we found that improved technology to detect the presence of CBW agents would improve the health surveillance of troops involved in future conflicts. The Committee made the following recommendations related to chemical and biological weapons in the *Interim Report*:

- CIA and DOD should coordinate their analyses to ensure a comprehensive review of the complete record of the Gulf War. Each agency should make full and prompt disclosure of all findings.
- DOD should devote more attention to monitoring low-level (subacute) exposures to chemical warfare agents. One possible basis for such a system is the automated air-sampling system developed by the U.S. Army Edgewood Research, Development and Engineering Center for the United Nations Special Commission on Iraq, which is using it to monitor emissions from Iraqi chemical plants. Another approach might be to modify the detection system the U.S. Army uses to monitor for leaks at chemical weapons storage depots.
- DOD should continue to invest in the development of a biological point detector/alarm system that can detect and identify biological warfare agent aerosols rapidly enough to enable troops to take protective measures before being exposed.

This section of the *Final Report* includes the Committee's assessment of the government's response to our *Interim Report* recommendations and includes additional findings and recommendations on issues related to chemical and biological weapons.

## DOD AND CIA RESPONSES



As described more fully later in this chapter, CIA has systematically reviewed classified and open source information related to CBW agent exposures during the Gulf War. In contrast, DOD has failed to take advantage of its unique access to both classified and routine military operations and intelligence records. DOD has not accepted or implemented the Committee's recommendation to develop and implement low-level CW agent monitoring. DOD has not made substantial progress in fielding a real-time biological agent detector.<sup>331</sup>

The Committee notes that in a series of studies since the end of the Gulf War in 1991, the U.S. General Accounting Office (GAO) has identified several inadequacies in the U.S. military's preparedness for chemical or biological attacks, and GAO has briefed the Committee on these matters.<sup>66,307,308</sup> While DOD has agreed with virtually all of GAO's findings and recommendations, the Committee is concerned that the equipment, training, and medical shortcomings still persist and could result in needless casualties and a degradation of U.S. war fighting capability.

### Issues New to This Report

To complete its evaluation of information related to reports of possible detections of CW or BW agents during the Gulf War, the Committee focused on two questions:

- What conclusions can be drawn about exposures given the evidence collected to date?
- How vigorously has the government pursued the search for evidence?

The Committee purposely separated these issues from its assessment of the possible health effects of CBW agents, which is discussed in chapter 4.

### Evidence of Exposure

Drawing from a number of sources, including interviews with veterans, operational and intelligence logs, UNSCOM reports, and testimony, briefings, and reports from CIA and DOD, the Committee reviewed evidence of exposure to CBW agents. Ultimately, we identified three possible exposure scenarios for analysis: intentional use of CBW agents by the Iraqis; theater-wide contamination from air war bombings in Iraq; and site-specific exposures related to bombings or demolition activities.<sup>279,313</sup> The Committee has drawn its conclusions with full knowledge that ongoing investigations could disclose additional evidence and does not intend for our work to foreclose full consideration of new information.

**Exposure to biological warfare agents.** The Committee's review of U.S. Army hospital admissions records identified only one admission for anthrax (a disease indigenous to the Gulf region) and none for botulinum poisoning. Stateside laboratory analyses also have not indicated BW agents were present in the KTO. Reports of dead animals that could have succumbed to biological warfare agents have been investigated by DOD, and the evidence does not implicate biological warfare. Finally, Iraqi officials have denied any use of biological weapons during Operations Desert Shield/Desert Storm. Thus, the best evidence available to the Committee indicates U.S. personnel were not exposed to biological warfare agents during the Gulf War.<sup>35,51,52,119,148,274</sup>

This conclusion is based on imperfect information. For instance, UNSCOM cannot verify the quantities and weaponization status of Iraqi BW agents because Iraq claims it unilaterally destroyed all of its biological weapons.<sup>51,162</sup> Additionally, the United States did not deploy a real-time BW agent detection system to the Gulf.

**Intentional Iraqi use of chemical warfare agents.** Iraq successfully used chemical weapons in its war with Iran, with massive casualties not seen in the Gulf War. A DOD review of U.S. Army hospital admissions records identified no admissions for CW agent exposures. The U.S. Army officer responsible for CBW agent medical surveillance during the war has testified to the Committee that only one, accidental casualty was treated (discussed below). Additionally, UNSCOM reported to us that Iraqi officials have denied to them any use of chemical weapons during the war. Lastly, veterans groups

testifying before this Committee concede there were no widespread chemical attacks. Based on information compiled to date, there is no persuasive evidence of intentional Iraqi use of CW agents during the war.<sup>35,51,52,119,148,249,261,274</sup>

Again, the best available information is less than ideal. Iraqi representations cannot always be taken at face value. And, some veterans have not received satisfactory explanations for wartime incidents they believe involved chemical weapons.<sup>74,144,249,323</sup>

**Theaterwide chemical warfare agent contamination from air war bombings of Iraq.** During the Gulf War, Coalition forces conducted air attacks on suspected Iraqi CW agent manufacturing and storage facilities. Some veterans and independent researchers have suggested that fallout from Coalition bombing of these sites led to large-scale nerve agent contamination in the KTO.<sup>261,313</sup> The Committee looked at evidence of the effects of Coalition airstrikes on Iraqi chemical munitions storage sites to examine this hypothesis.

In late January and February 1991, Coalition forces conducted aerial bombings that damaged chemical munitions stored at two sites in central Iraq: Muhammadiyat and Al Muthanna. Subsequent UNSCOM investigations indicate these are the only sites (among 11 known storage sites) where Coalition airstrikes actually damaged or destroyed chemical agents. At Muhammadiyat, munitions containing 2.9 metric tons of sarin/cyclosarin and 15.2 metric tons of mustard were damaged during the air war. At Al Muthanna, munitions containing 16.8 metric tons of sarin/cyclosarin were damaged during the air war.<sup>35,51,148,274</sup>

To assess possible hazards to U.S. forces from CW agent releases at Muhammadiyat and Al Muthanna, atmospheric modeling was conducted for the CIA for all possible bombing dates at each site. This modeling indicates that on the bombing date when southerly winds were most pronounced, Muhammadiyat releases, at worst, would have resulted in downwind contamination for up to 300 kilometers (km) at general population exposure levels established by DOD. This modeling also indicates that on the bombing date when southerly winds were most pronounced, Al Muthanna releases, at worst, would have resulted in downwind contamination for up to 160 km at general population exposure limits. (The general population exposure is a threshold at which one would not expect to see characteristic signs and symptoms of CW agent exposure.) During the air war, the nearest U.S. personnel were in Rafha, Saudi Arabia-more than 400 km from Muhammadiyat and Al Muthanna. Figure 2-2 depicts the locations of the damaged munitions and the closest U.S. forces during the Gulf War.<sup>35,51,148,158,162,274</sup>

The Committee frequently heard the suggestion that air strikes on An Nasiriyah caused CW agent contamination as far away as King Khalid Military City, Saudi Arabia.<sup>261,313</sup> Onsite inspections by UNSCOM, however, found no evidence that chemical munitions were damaged at An Nasiriyah. Iraqi officials also have stated to UNSCOM that chemical munitions stored there were moved to Khamisiyah when An Nasiriyah was first subjected to airstrikes, although the Iraqis have not cooperated fully with the UNSCOM investigations.<sup>51</sup> The best evidence available, indicates theaterwide contamination with CW agent fallout from the air war is highly unlikely.<sup>35,158,274,281,330</sup>

**Site-specific chemical agent exposures.** During the period U.S. forces were deployed in the KTO, incidents occurred at specific sites that resulted in confirmed exposure, detection, or release of CW agents. In testimony and submissions to this Committee, DOD has taken the position that chemical agent exposures can be confirmed only through physical symptoms.<sup>119,148</sup> The Committee believes this approach is analytically flawed and that medical symptoms should not drive a determination of presumed exposure/nonexposure.

**Confirmed mustard agent exposure.** On March 1, 1991, a soldier exploring a captured bunker in southern Iraq suffered a burn that DOD now confirms was caused by mustard agent. Two mass spectrometer tests by Fox vehicles detected mustard agent on the flak jacket worn by U.S. Army Sergeant Fisher, who was diagnosed as suffering from a chemical agent burn. DOD does not view negative results from subsequent laboratory tests on the jacket and urinalysis as inconsistent with the signs of low-level

exposure exhibited by the soldier. DOD now acknowledges the site-specific exposure of mustard agent of this individual.<sup>13,52,148,279,323</sup>

Confirmed nerve and mustard agent detections. On January 19, 1991, shortly after the beginning of the air war, Czech units reported detecting nerve agent at two locations northeast of Hafir al Batin, Saudi Arabia. On January 24, 1991, Czech units also reported detecting mustard agent at a site 10 km north of King Khalid Military City, Saudi Arabia. DOD has verified the reliability of the Czech equipment and regards these detections as valid, but cannot identify a source of the CW agents for either detection.<sup>13,148,281,330</sup> The Czech detections represent un rebutted evidence of the presence of CW agents at these sites, and low-level exposure-at the detection sites-must be presumed.

As noted earlier in this section, worst-case modeling of known CW agent releases at Muhammadiyat and Al Muthanna indicates potential contamination would not have reached the Czech forces. Although there is no evidence of CW agent release from bombing of An Nasiriyah, worst-case modeling conducted for CIA also eliminates this hypothetical release as the source of the Czech detections-i.e., evidence indicates An Nasiriyah, Muhammadiyat, and Al Muthanna were not the CW agent sources for the positive Czech findings. This inability to identify a source for the Czech-detected CW agents precludes modeling the range of exposures around the detection sites. CW agents also were not detected by U.S. troops sent to confirm the Czech findings. Currently, it is not possible to identify low-level exposure of any U.S. troops associated with these two Czech detections.<sup>13,35,51,148,158,274,281,330</sup>

Confirmed nerve agent releases at Khamisiyah. In the ceasefire period after the ground war concluded, U.S. personnel used explosives to destroy captured munitions and other materiel throughout occupied areas of southern Iraq so that enemy forces could not use them to rearm. One such site was a major storage depot at Khamisiyah, where more than 100 large bunkers containing artillery rounds, rockets, and other munitions were destroyed in March 1991.<sup>119,147,148</sup>

DOD has testified to the Committee that on March 4, 1991, U.S. personnel destroyed munitions containing 8.5 metric tons of sarin/cyclosarin housed in Bunker 73 at Khamisiyah. On March 10, 1991, U.S. personnel destroyed an as yet unknown number of sarin/cyclosarin rockets at a pit area at Khamisiyah.<sup>119,148</sup>

Atmospheric modeling conducted for CIA indicates CW agent release from Bunker 73 would result in downwind contamination for up to 25 km at general population exposure limits<sup>35,158</sup> (figure 2-3). U.S. personnel with the 37th Engineering Battalion, 307th Engineering Battalion, 60th Explosive Ordnance Detachment, 146th Explosive Ordnance Detachment, 450th Civil Affairs Battalion, and other components of the 82nd Airborne Division were within 25 km of Khamisiyah.<sup>58,119,147,148</sup> The footprint of the March 10, 1991, release and other possible releases at the Khamisiyah pit area are still under investigation.<sup>230,331</sup>

The evidence of CW agent release at Khamisiyah is overwhelming. The Committee concludes exposure should be presumed for nearby troops, although the exact levels are unknown. The presumption of exposure does not include a presumption of long-term health effects (see chapter 4). As of this writing, DOD has initiated an effort to notify all troops within a 50 km radius around Khamisiyah between March 4 to March 13, 1991, that they could have been exposed to low levels of CW agents.<sup>331</sup> These actions appear prudent in light of what is known about the destruction of Bunker 73, but additional steps could be necessary once the full extent of Khamisiyah demolition activities is known.

## Search for Evidence

The U.S. government has relied on CIA and DOD internal investigations to report evidence of exposure of U.S. troops to CBW agents. CIA was assigned two responsibilities: reviewing intelligence information relevant to possible CBW agent exposures and performing downwind hazard modeling for possible CW agent releases.<sup>35</sup> DOD's investigatory efforts have been led by PGIT, which reports to the Assistant Secretary of Defense (Health Affairs). PGIT's scope spans the broad range of issues related to

Gulf War veterans' illnesses. Additionally, a DOD Senior Level Oversight Panel for Gulf War veterans' illnesses coordinates the declassification and release of documents related to CBW agents and other potential risk factors.104,119,325

**CIA's investigation.** In March 1995, CIA began a *de novo* review of intelligence related to CBW agents and the Gulf War; its work in atmospheric modeling began in early 1996. To date, CIA has aggressively pursued information related to possible CBW agent exposures from classified and open sources. With respect to downwind hazard modeling, CIA has been responsive to the Committee's concerns about potential low-level contamination and has modified modeling assumptions and parameters to reflect these concerns. In August 1996, CIA reported on the bulk of its analysis but the agency has yet to complete atmospheric modeling for the March 10, 1991, destruction at the Khamisiyah pit area.35,158,230,274

**DOD's investigations.** Since 1991, DOD's public position has been there was no use or presence of chemical weapons in the KTO, and no U.S. troops were exposed to CBW agents during the Gulf War. DOD maintained this position throughout a series of congressional investigations in late 1993 and early 1994. In June 1994, a DSB Task Force concluded there was "no evidence that either chemical or biological warfare was deployed at any level against us, or that there were any exposures of U.S. service members to chemical or biological warfare agents in Kuwait or Saudi Arabia." The DSB Task Force was silent on the issue of exposures to service members in Iraq, but its conclusion was interpreted by DOD as inclusive.119,279,313

**Persian Gulf Veterans' Illnesses Investigation Team.** PGIT's 12-member staff includes intelligence officers, members of the Chemical Corps, pilots, chemists, physicians, and one trained investigator. Reflecting its staffing, PGIT has devoted substantial resources to literature reviews and scientific studies, rather than collecting first-hand evidence of possible CBW agent exposure incidents from eye witnesses, battlefield intelligence, unit logs, diaries, and other original documents. By doing so, PGIT has failed to take advantage of its unique access to classified and routine military records to fully investigate and help answer the public's questions about possible CBW agent exposures.119,148,163,169 PGIT's investigation of the Khamisiyah incidents represents the sole exception to this situation.

Khamisiyah first appeared on PGIT's list of incidents under investigation in October 1995 material supplied to the Committee. Yet, PGIT conducted no interviews with possible eyewitnesses until June 1996. PGIT had knowledge of documents, including UNSCOM reports and declassified intelligence reports posted to GulfLINK, that suggested a sufficient basis to initiate investigatory interviews long before UNSCOM confirmed in May 1996 its initial reports about the presence of CW agents. PGIT's recent eyewitness interviews and its efforts to ascertain troop locations have been valuable, however, in trying to find answers about the Khamisiyah incidents.119,325

More importantly, other possible CW agent incidents also merit a thorough review and full investigation. Chief among these are positive readings recorded by two types of detectors fielded to verify chemical agent alarms: Fox reconnaissance vehicles equipped with mobile mass spectrometers and M256 kits, which employ enzymatic tests for nerve agents and chemical tests for blister agents. Fox reconnaissance vehicles detected blister and nerve agents at various sites in Kuwait and Saudi Arabia, and M256 kits also detected the presence of CW agents during the ground war.74,144,249,323 Rather than thoroughly investigate these site-specific incidents, PGIT plans to include them in a theater-wide time/distance analysis.119,148

In response to our questions in May 1996 about potential low-level CW agent exposures, PGIT first reported it had no formal, objective standard(s) for assessing whether CBW agent detections should be confirmed or not confirmed. Two months later in July 1996, PGIT reported to the Committee that it had adopted military CBW agent detection standards to confirm the occurrence of an exposure. This standard requires both agent detections and physical symptoms of poisoning.119,148

The Committee faults PGIT on two counts in this regard: first, for its delay in adopting standards until,

as PGIT admitted, it was pressed by the Committee more than a year after it began its work; and second, for confusing the matter of potential CW agent exposure with the separate issue of possible health effects of CW exposure. Adherence to this standard—even when assessing possible low-level exposures that do not cause immediate physical symptoms—has severely undermined public confidence in DOD's work on CBW agent issues. PGIT's analyses related to CBW incidents have lacked vigor, fallen short on investigative grounds, and stretched credibility.

In November 1996, DOD introduced some organizational changes related to its work on Gulf War veterans' illnesses. As part of this reorganization, DOD announced plans to revamp its investigatory and research programs related to low-level CW agent exposure.<sup>331</sup> These efforts, combined with publicly visible, independent, high-quality oversight, could begin to restore public confidence in the government's investigations of possible incidents of CW agent exposure.

Enhancing public access to information. DOD's slow and erratic efforts to release information to the public have further served to erode the public's trust. As of December 1996, 5 of 54 PGIT investigations have generated reports posted on DOD's GulfLINK Internet site. DOD typically has posted testimony before this Committee on GulfLINK, but the department has not posted status reports on its investigations that it prepared for the Committee in August 1996.<sup>119,325</sup> Public access to more information could only enhance DOD's reputation among parties interested in these issues.

DOD's pledge to post copies of relevant declassified documents to GulfLINK also has proved problematic. In November 1995, DOD officials instructed that before declassifiers posted sensitive documents, they should forward the material to PGIT "to allow the investigation Team time to begin preparation of responses on particular 'bombshell' reports".<sup>324</sup> Separately in February 1996, nearly 400 declassified documents were removed from GulfLINK due to security concerns of CIA.<sup>230</sup> DOD reported to the Committee that the documents were not reclassified, but the documents were not restored to GulfLINK until November 1996.<sup>331</sup> These actions clearly have created the impression that the government, particularly DOD, has failed to live up to repeated assertions and commitments to openness in its work related to CBW agent investigations and the Gulf War.<sup>119,144,163,249,325</sup> Nationwide, there has been an increasingly strongly held view that DOD is still withholding relevant information from concerned veterans and the public.

## **Findings Regarding Chemical and Biological Weapons**

Based on interviews with veterans, review of operational and intelligence logs, UNSCOM reports, testimony, briefings, and reports from CIA and DOD, the Committee makes the following findings:

- In the face of credible evidence of the presence or release of chemical warfare agents, low-level exposure of U.S. personnel at the affected site must be presumed while efforts to develop more precise measures of exposure continue.
- The evidence of chemical warfare agent release at Khamisiyah is overwhelming, and low-level exposure to troops within a 50 kilometer radius should be presumed while efforts to develop more precise measures of exposure and more detailed knowledge of the demolition activities continue.
- Other site-specific exposures of U.S. troops to low levels of chemical warfare agents cannot be ruled out. A theater-wide time/distance analysis is insufficient to address positive detections by Fox reconnaissance vehicles and M256 kits.
- DOD has conducted a superficial investigation of possible chemical warfare agent exposures that is unlikely to provide credible answers to veterans' and the public's questions.

The Committee's recommendations for governmental actions based on these findings appear on page 54 of the printed version of the *Final Report*.

## **COORDINATION**

The President established the Coordinating Board on January 21, 1994, to provide direction and coordination on health issues related to the Gulf War within the executive branch of the federal

government. Earlier in this chapter, we reviewed the role of the Coordinating Board's RWG in managing the Gulf War veterans' health research of DOD, VA, and DHHS. Here we analyze the RWG's other tasks and also evaluate the Coordinating Board's two other working groups: the Clinical Working Group (CWG) and the Disabilities and Benefits Working Group (DBWG). Finally, we have assessed the government's ability to respond to the broad range of issues—from the need for medical care and outreach services, to the need for research on general and specific health concerns—likely to arise after future conflicts.

### **Coordinating Efforts Specific to Gulf War Health Issues**

The Secretaries of DOD, DHHS, and VA head the Coordinating Board. The Coordinating Board's three primary missions are:

- to provide all veterans the complete range of health care services necessary for medical problems that might be related to deployment in Operations Desert Shield/Desert Storm;
- to develop a research program that will result in the most accurate and complete understanding of the types of health problems being experienced by Gulf War veterans and the factors that have contributed to these problems; and
- to develop clear and consistent guidelines for the evaluation and compensation of disabilities related to Gulf War service.<sup>2</sup>

The Coordinating Board established a working group to oversee each primary mission. As a preliminary matter, the Committee found the assistance of the Coordinating Board and participants in the working groups invaluable. In addition, we recognize the difficulty of integrating the activities of large departments with disparate missions to achieve a whole greater than the sum of its parts. The Committee commends the dedication of the staff involved in these efforts.

**Clinical Working Group.** The CWG oversees delivery of care to Gulf War veterans. The Committee found that, overall, high-quality health care is provided. We recommend, however, some improvements in CME and a regular review of staffing requirements to ensure adequate access to follow-up care.

VA introduced its clinical Registry program in 1992 and refined the physical examination and associated questionnaires over the next two years; DOD and civilian medical professionals were consulted as the program matured. DOD adopted VA's standardized evaluation protocol for its CCEP in 1994, and both departments continue to use the same protocol. This Committee and others have judged the protocol to be an excellent tool for diagnosing illness.

The CWG serves as a useful counterpart to the RWG by ensuring coordination of the research plan with interesting hypotheses that might emerge from the clinical programs. The CWG also has an important role to play in disseminating information about the clinical programs and in communicating the results of the research program to health professionals in DOD and VA medical facilities.

**Research Working Group.** In its *Interim Report*, the Committee identified the need for a more aggressive stance by the RWG in emphasizing the importance of utilizing peer review committees when planning and conducting research and in coordinating the design of epidemiologic surveys. Overall, the RWG has been responsive to our recommendations. A peer review process was used to identify scientifically meritorious proposals that were funded in 1996 (in response to DOD's BAA issued in 1995). Ongoing government-sponsored epidemiologic surveys of Gulf War populations include a core set of similar questions regarding symptoms and exposures that should enable appropriate comparisons among study groups. Future investigators will be encouraged to incorporate the RWG-developed set of core questions in their work.

The RWG has set priorities for new research on Gulf War veterans' illnesses. And the group has overseen the publication of research compendiums and efforts to cooperate with U.S. allies in the Gulf War in future health research.

**Disabilities and Benefits Working Group.** The DBWG initially addressed itself to a broad range of

issues, including case definitions for disabilities with vague symptoms, care for family members of Gulf War veterans, and DOD's outreach program on Gulf War veterans' health issues. Late in 1994, this working group took as its primary responsibility coordination of the executive branch response to Public Law 103-446, which authorized compensation to Gulf War veterans for disabilities resulting from undiagnosed illnesses. VA issued an implementing regulation (38 CFR 3.317) in February 1995. The DBWG continued to meet through June 1995 to discuss the impact of the new legislation and regulation. The only meeting in 1996 to date occurred for the purpose of briefing this Committee's staff on pay and benefits for individuals separated from service; DOD's disabilities evaluation process; military retirement and separation for disability; comparison of the departments' use of VA's schedule for rating disabilities; and VA's compensation and evaluation procedures.

VA currently is reviewing how effectively it has managed its program of compensation for undiagnosed illnesses. A randomized case review by VA's Compensation and Pension Service (prompted, in part, by a GAO report<sup>310</sup>) disclosed frequent instances of miscategorization in the tracking system and failures to develop evidence-particularly lay observations-that might affect the outcome of a claim. As a result of this review, VA reported to the Committee that as of July 1996, it had undertaken a complete second review of all 11,000 cases in the tracking system to ensure full evidentiary development, correct adjudication, and accurate coding in the tracking system. VA also issued more detailed instructions emphasizing these points. VA expected the review of 11,000 cases to take six months and reported its intent to work closely with DOD.

### **Anticipating Post-conflict Health Concerns**

Several concerns identified during the Committee's examination of Gulf War veterans' illnesses-issues related to research, outreach, and clinical programs-have surfaced after previous conflicts (e.g., effective epidemiology in the absence of baseline exposure and health information; risk communication with veterans concerned about environmental hazards; and uncertainties about the health consequences of environmental exposures). Responsibility for resolving concerns that invariably arise in the aftermath of military conflicts lies within the domain of several departments, yet appears to be a principal focus of no agency. Following a military operation, effort is exerted in a reactive, rather than proactive, manner.

The departments principally involved in Gulf War veterans' illnesses-DOD, VA, and DHHS-have had historical responsibilities for other, similar post-conflict issues, but a number of other agencies also have important expertise and interest. These entities include EPA, CIA, the Department of Energy, the National Science Foundation, the Department of Commerce, and the Department of State. Along with DOD, VA, and DHHS, all are members of the National Science and Technology Council (NSTC), an interagency coordinating body established to ensure cross-agency attention to matters of critical national importance.

The lessons learned from the Committee's analyses of Gulf War veterans' health concerns point toward post-conflict health needs of veterans as precisely such a matter. A Presidential Review Directive to the NSTC could be used to ensure the government formulates a comprehensive strategy to deal with key concerns that arise following significant military operations, including:

- health (e.g., stress prevention, treatment, research; medical surveillance adequacy, coordination; interventions for families);
- outreach and risk communication;
- recordkeeping (e.g., accountability, timeliness, cross-agency coordination, application of new technologies);
- research (e.g., adequacy, quality, coordination, dissemination of results);
- biological and chemical weapons preparedness and research;
- application of emerging technologies (e.g., telemedicine, technology transfer); and
- international cooperation and coordination, especially on research and technology matters.

Any plan developed by NSTC should be reviewed by appropriate nongovernmental experts to ensure that these recurring concerns receive attention at the highest national levels.



## Finding Regarding Coordination

Based on its analysis of the government's efforts to coordinate the response to Gulf War veterans' illnesses, the Committee makes the following finding:

- Many issues related to post-conflict health concerns of Gulf War veterans are common to the aftermath of other military engagements. Governmental responsibility to address such concerns spans the missions of several federal departments and agencies, but is a priority for no agency. Resolving these issues in a timely and effective manner requires interagency coordination at the highest levels of government.

The Committee's recommendation for governmental action based on this finding appears on page 55 of the printed version of the *Final Report*.

## SUMMARY

The President asked that we review the full range of government activities relating to Gulf War veterans' illnesses. In the *Interim Report*, we organized our analyses of the government's efforts into four broad areas: outreach, medical and clinical issues, research, and chemical and biological weapons. In this document, we make additional findings and recommendations to complete our initial assessments in these areas; we also address coordination for the first time.

With the exception of DOD's investigations in matters related to incidents involving chemical weapons and possible exposure to U.S. troops, we believe the government has acted in good faith and drawn on a somewhat checkered experience with Agent Orange to significantly improve how it has addressed Gulf War veterans' health issues. Hence, we note that although our recommendations are many, they are offered to improve the government's generally commendable response. Their number and scope should not be viewed as a wholesale condemnation or cause for a complete overhaul of the government's approach to addressing the health concerns of Gulf War veterans.

## RECOMMENDATIONS

The Committee's evaluation of the government's response to concerns about Gulf War veterans' illnesses led us to findings in outreach, medical and clinical issues, research, chemical and biological weapons, and coordination. Based on our analyses and these findings, the Committee makes the following recommendations:

### Outreach

- DOD and VA should follow the model of field-based outreach demonstrated in the Vet Centers and the Persian Gulf Family Support Program when developing health education and risk communication campaigns for active duty service members, Reserve and National Guard personnel, and other veterans. General, less specific outreach methods-e.g., hotlines and public service announcements-should be viewed as important supplements, but not as replacements.
- VA should direct its Transition Assistance Program workshop benefits counselors to specifically mention DOD and VA programs related to Gulf War veterans' illnesses.
- VA should ensure that its initiatives under the Women Veterans Health Programs specifically provide information about Gulf War-related programs.
- VA should ensure that its outreach to Latino populations specifically provides information about Gulf War-related programs. As the Committee stated in its *Interim Report*, DOD and VA should develop and utilize more refined performance measures to determine how well outreach services are reaching concerned parties. DOD and VA officials (specifically those in the American Forces Information Service and its broadcasting arm, the Armed Forces Radio and Television Service) using media products for outreach initiatives should be aware of the difficulty in enumerating the actual readership and viewership figures and be concerned about how effectively their message saturates the targeted population.
- DOD should reissue its *Internal Information Plan* on Gulf War-related illnesses. It should make a



special effort to note the revision provides the toll-free number and that individuals are encouraged to register for its Comprehensive Clinical Evaluation Program. It also should take this opportunity to provide updated information.

- In an attempt to increase veterans' and the public's awareness and understanding of the full range of the government's commitment to addressing the nature of Gulf War veterans' illnesses, DOD and VA should reevaluate the goals and objectives of their risk communication efforts. DOD and VA should develop effective methods that provide the affected community with comprehensive information concerning possible exposures to environmental hazards, potential health effects from risk factors, and explanations of ongoing and completed clinical and epidemiologic studies.
- DOD and VA should immediately develop and implement a comprehensive risk communication plan. This effort should move forward in close cooperation with agencies that have a high degree of public trust and experience with risk communication, such as the Agency for Toxic Substances and Disease Registry and the National Institute for Occupational Safety and Health.
- Because health risk information and education applies to service members who remain on active duty, members of the Reserves and National Guard, and veterans no longer in military service, DOD and VA should closely coordinate the federal government's risk communication effort for Gulf War veterans and other members of the affected community. Departmental commitments to any plan should be viewed as continuous and long-term; a sustained effort is particularly critical in light of veterans' and public skepticism arising from the recent revelations related to chemical weapons.
- In its coordinated risk communication plan, DOD and VA should engage veterans service organizations as intermediaries-and include personnel in leadership positions, such as senior enlisted personnel (for active duty military) and state veterans' service officials-in the effort to establish an efficient information exchange process where veterans receive accurate information and the departments receive valuable feedback on clinical programs, health concerns, and communication efforts.

## Medical and Clinical Issues

- Given that the Food and Drug Administration's (FDA) Interim Final Rule permitting a waiver of informed consent for use of unapproved products in a military exigency is still in effect, DOD should develop enhanced orientation and training procedures to alert service personnel they may be required to take drugs or vaccines not fully approved by FDA if a conflict presents a serious threat of chemical and biological warfare.
- FDA should solicit timely public and expert comment on any rule that permits waiver of informed consent for use of investigational products in military exigencies. Among the areas that specifically should be revisited are: adequacy of disclosure to service personnel; adequacy of recordkeeping; long-term followup of individuals who receive investigational products; review by an institutional review board outside of DOD; and additional procedures to enhance understanding, oversight, and accountability.
- DOD officials at the highest echelons, including the Joint Chiefs of Staff and the Commanders in Chief, should assign a high priority to dealing with the problem of lost or missing medical records. A computerized central database is important. Specialized databases must be compatible with the central database. Attention should be directed toward developing a mechanism for computerizing medical data (including classified information, if and when it is needed) in the field. DOD and VA should adopt standardized recordkeeping to ensure continuity.
- The Persian Gulf Veterans Coordinating Board and other appropriate Departments and Agencies should be charged to develop a protocol to implement the following recommendation, which was made in the Committee's *Interim Report*: Prior to any deployment, DOD should undertake a thorough health evaluation of a large sample of troops to enable better postdeployment medical epidemiology. Medical surveillance should be standardized for a core set of tests across all services, including timely postdeployment followup.
- VA and DOD should, in their educational outreach programs, specifically target staff members not directly involved in the care of Gulf War veterans.
- DOD and VA should include timely updates on the Comprehensive Clinical Evaluation Program or Persian Gulf Health Registry, respectively, in their Continuing Medical Education programs.
- VA and DOD should regularly brief their staffs on the Gulf War research portfolio and on the

results of research studies as they become available.

- VA and DOD should regularly review staffing needs, particularly in mental health, and increase recruitment and retention of adequate numbers of medical professionals to satisfy patient needs. Staffing reviews should consider that, despite increased medical surveillance and better preventive measures, future deployments also will generate a significant number of veterans who will need care for illnesses that are difficult to diagnose.
- Since 1986, U.S. service members with certain chronic illnesses, e.g., asthma and diabetes, have been allowed to remain on active duty when regular medical monitoring is necessary. Veterans of the Gulf War with chronic illnesses are no different. Troop commanders should be reminded that adequate time off for follow-up medical appointments is a necessity and a priority.
- The government should conduct a thorough review of its policies concerning reproductive health and seek statutory authority to treat veterans and their families for service-connected problems. When indicated, genetic counseling should be provided either via VA treatment facilities or referral to assist veterans and their families who have reproductive concerns stemming from military service.
- The government should continue and intensify its efforts to develop stress reduction programs for all troops, with special emphasis on deployed troops.
- Since leadership and unit cohesion are so important in managing stress, DOD should specifically involve senior commanders and senior noncommissioned officers in stress management programs.

## Research

- The Research Working Group of the Persian Gulf Veterans Coordinating Board should require that any proposals for new, large-scale Gulf War veterans' epidemiologic health research describe a plan to incorporate a public advisory committee into the study design, dissemination of results, or both. The Research Working Group should consider justifying a waiver of such a committee only under rare circumstances.
- The government should develop more accurate and reliable methods of recording troop locations to facilitate post-conflict health research in the future. DOD should make full use of global positioning technologies.
- The government should plan for further research on possible long-term health effects of low-level exposure to organophosphorus nerve agents such as sarin, soman, or various pesticides, based on studies of groups with well-characterized exposures, including: a) cases of U.S. workers exposed to organophosphorous pesticides; and b) civilians exposed to the chemical warfare agent sarin during the 1994 and 1995 terrorist attacks in Japan. Additional work should include followup and evaluation of an appropriate subset of any U.S. service personnel who are presumed to be exposed during the Gulf War. The government should begin by consulting with appropriate experts, both governmental and nongovernmental, on organophosphorus nerve agent effects. Studies of human populations with well-characterized exposures will be much more revealing than studies based on animal models, which should be given lower priority.
- Since a number of Gulf War risk factors are potential human carcinogens that could result in increased rates of cancer beginning decades after exposure, VA should continue to monitor Gulf War veterans through its ongoing mortality study for increased rates of lung, liver, and other cancers.
- Depleted uranium munitions are likely to be used in future conflicts involving U.S. service personnel. To fully elucidate the health effects of depleted uranium munitions, VA should conduct research that compares the health status of individuals with embedded fragments of DU shrapnel with appropriate control groups.
- The government should continue to collect and archive serum samples from U.S. service personnel when feasible.
- The Research Working Group should more thoroughly consult with other federal agencies with relevant expertise such as the National Institutes of Health (particularly the National Institute of Environmental Health Sciences) and the Agency for Toxic Substances and Disease Registry on basic, clinical, and epidemiologic research and on risk communication.

## Chemical and Biological Weapons

- All U.S. service personnel assigned to units near the Khamisiyah demolition activity should be notified and encouraged to enroll in VA's Persian Gulf Health Registry or DOD's Comprehensive Clinical Evaluation Program. In determining the extent of possible chemical warfare agent exposure at Khamisiyah and any other sites that future investigations uncover, the government should use the best theoretical and practical assessment tools available. The Committee recognizes the large number of variables that can affect the outcome of any determination, but identifies the following as essential principles:
  - Where objective, un rebutted evidence suggests the release of chemical warfare agents in the vicinity of U.S. troops, every effort should be made to identify the source of the agent and to model the downwind footprint of the potential distribution of agent at the general population exposure level (or lower threshold, if appropriate);
  - When a downwind footprint is established, a conservative, presumptive-exposure area should be defined that reflects the uncertainties of the modeling effort. The presumptive-exposure area should, at a minimum, include all sites within a circle that has a radius equal to the length of the downwind footprint; and
  - Troops within the presumptive-exposure area should be notified and encouraged to enroll in the CCEP or Registry.
- All reports of positive M256 kits and Fox detections must be thoroughly investigated. Where unit logs record positive detections by either type of equipment, members of that unit should be notified and encouraged to enroll in VA's Persian Gulf Health Registry or DOD's Comprehensive Clinical Evaluation Program.
- To ensure credibility and thoroughness, further investigation of possible chemical or biological warfare agent exposures during the Gulf War should be conducted by a group independent of DOD. Openness in oversight activities-including public access to information and veteran participation-public notice of meetings, opportunity for public comment, and regular reporting are essential. Full public accountability is critical.

## Coordination

- A Presidential Review Directive (PRD) should be issued to instruct the National Science and Technology Council to develop an interagency plan to address health preparedness for and readjustment of veterans and families after future conflicts and peacekeeping missions. The President's Committee of Advisors on Science and Technology and other nongovernmental experts, as appropriate, should be asked to review the plan 12 months after the PRD is issued and again at 18 months to ensure national expertise is brought to bear on these issues.

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\*These services were designed to manage post-traumatic stress disorder, which was the primary readjustment concern.

\*\*Initially, treating post-traumatic stress disorder was the PGFSP's primary focus of clinical services.

\*\*\*At DOD's request, the Institute of Medicine (IOM) evaluated the CCEP, and IOM judged the clinical protocol (also used by VA) excellent for the diagnosis of illnesses. <sup>95</sup>

## **Presidential Advisory Committee on Gulf War Veterans' Illnesses Final Report**

### **Chapter Two**

## **THE GOVERNMENT'S RESPONSE**

The President assigned the Committee two principal tasks:

- determine whether the government is doing all it can to discover the causes of Gulf War veterans' illnesses; and
- determine whether the government is delivering quality care to those veterans who are ill.

We initially addressed these questions in our *Interim Report*, which was delivered in February 1996. In the sections of this chapter on outreach, medical and clinical issues, research, and chemical and biological weapons, we include an assessment of how the government has responded to the Committee's *Interim Report* recommendations.

To complete our work, the Committee continued evaluating outreach regarding benefits and services available to Gulf War veterans and also evaluated the departments' risk communication efforts. Committee and staff also conducted a series of site visits to DOD and VA medical facilities, and evaluated the government's ability to respond to reproductive health concerns and the stresses of war. For this *Final Report*, the Committee has assessed the scope of the federally funded research portfolio and the award making process.

We make recommendations for improvement in each of these areas-outreach, medical and clinical issues, and research. Overall, however, the Committee commends the government's response to the range of health-related problems experienced by Gulf War veterans. Lessons were learned from our country's experience with the Vietnam War and the health effects of exposure to Agent Orange. For the most part, the government has acted in good faith and drawn on that experience to significantly improve its handling of Gulf War veterans' concerns.

The Committee is less sanguine about the government's investigation of incidents of possible exposure of U.S. troops to chemical and biological warfare (CBW) agents. Investigatory efforts have been slow and superficial, and no credible attempts to communicate with the public on these investigations have been made. Our most severe criticisms are reserved for this issue. Regrettably, DOD did not act in good faith in this regard.

The most striking feature of our evaluation of the government's response to Gulf War veterans' health issues has been the parallels between the experiences of these veterans and veterans of previous conflicts. We believe the government can do a better job of anticipating and preparing for post-conflict health problems. Thus, in assessing the government's coordination efforts, the Committee recommends an approach that would ensure all of the government's expertise is brought to bear on this issue of critical national concern.

### **OUTREACH**

In our *Interim Report*, the Committee examined some of the outreach programs of DOD and VA. We found they had used a number of progressive techniques-from establishing telephone hotlines for the health care programs that serve veterans to posting declassified documents on the Internet-to educate veterans and other citizens concerned about Gulf War veterans' illnesses. Neither department, however, had adopted performance measures sophisticated enough to evaluate the success of these programs. Our analysis revealed some relatively simple ways for DOD and VA to receive feedback on the utility of various outreach programs and a critical need to present information more clearly to veterans. As a result, our *Interim Report* included the following recommendations:

- Operators at the DOD Medical Registry Hotline, DOD Incident Reporting Line, and VA Helpline should be instructed to ask "How did you find out about this number?" as a method of qualitatively measuring the success of the different methods for publicizing the numbers.
- In the next Comprehensive Clinical Evaluation Program end-of-evaluation questionnaire, which participants answer when the initial evaluation is completed, DOD should include a question about satisfaction with the referral provided by the Persian Gulf Medical Registry Hotline.
- DOD and VA should utilize more refined performance measures to determine how well outreach services are reaching concerned parties. Caller volume data are not adequate.
- To assist the general public in interpreting the declassified intelligence documents on GulfLINK (a DOD site on the World Wide Web), DOD should prepare a user's guide. This guide should explain in general terms the various sources of intelligence information, how they may differ in quality and reliability, and how intelligence analysts compile and evaluate reports from a variety of sources in the field to obtain corroboration before preparing a final assessment. This guide should be featured prominently on the GulfLINK home page.
- In its outreach campaign, VA should forego use of the term "priority care." VA should state clearly that Gulf War veterans are entitled to receive the Persian Gulf Health Registry examination free of charge, including any diagnostic testing found to be medically necessary and counseling regarding findings.
- VA should make its broadcast public service announcements (PSAs) about the toll-free Helpline more explicit. The PSAs should include brief explanations of the purpose of the Helpline and the referral process for the Persian Gulf Health Registry.
- Future conflicts are likely to generate controversial and unexplained health concerns, and DOD and VA should anticipate the need and plan for outreach services and implement them expeditiously.

The following section of the *Final Report* includes the Committee's assessment of the government's response to our *Interim Report* recommendations and includes additional findings and recommendations concerning outreach.

## Departmental Responses

The departments have been responsive to these recommendations. Full implementation will require a long-term commitment that the Committee is not in a position to evaluate.

## Issues New to This Report

To complete our work, the Committee continued the evaluation of outreach to Gulf War veterans concerning benefits and medical services. In addition, we examined the issue of risk communication and whether DOD and VA are communicating effectively with Gulf War veterans about the health risks associated with service in Southwest Asia.

## Outreach Concerning Benefits and Medical Services

For this report, the Committee evaluated outreach efforts (i.e., education and publicity) associated with special government-sponsored readjustment programs, outreach to specific populations of Gulf War veterans, and military broadcasts.

**Outreach component of readjustment programs.** Immediately following the Gulf War, VA's Vet Centers and Persian Gulf Family Support Program (PGFSP) provided services to assist Gulf War veterans and their families in the post-conflict readjustment process. VA's staff for these programs performed a significant amount of outreach about the readjustment services available to active duty and veteran populations. As veterans began to report illnesses and as the government established clinical procedures to evaluate Gulf War veterans, the outreach aspects of Vet Centers and PGFSP continued to educate the public. Both programs quickly mobilized comprehensive outreach efforts and offered a more targeted and directed approach than subsequent DOD or VA efforts, which focused on hotlines and PSAs.

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**Vet Centers.** Congress authorized Vet Centers in 1979. The centers initially offered a range of services to Vietnam veterans, including psychotherapy and counseling, referral and aftercare for substance abuse,

to Vietnam veterans, including psychotherapy and counseling, referral and aftercare for substance abuse, crisis intervention for acute symptoms, employment and educational counseling, assistance with upgrade of military discharge, education of community professionals and the public, consultation and input into VA assessments and service decisions at VA Medical Centers (VAMCs), and intensive networking and referral interactions with other community agencies.\* VA's Readjustment Counseling Service (RCS) administers the Vet Center program.

All veterans of conflicts are eligible for Vet Center services. In 1991, RCS directed Vet Center staff to educate themselves about the Gulf War experience by setting up briefings with recent active duty and veteran returnees.

Information gathered via the briefings was presented to an RCS committee, which decided to place programmatic emphasis on meeting the special needs of women veterans and families of veterans. Vet Center staff have seen more than 69,000 Gulf War clients since May 1991. Gulf War clients comprise the largest percentage of the post-Vietnam era group of clients during this period.<sup>297</sup>

Vet Centers operate with considerable autonomy. Each center is staffed by a team leader-typically a social worker or clinical or counseling psychologist-two or three counselors, and an office manager staff. Most centers are nonthreatening spaces located away from the local VAMC (which continues to provide administrative support in the form of supplies, personnel, fiscal processing, and other logistical services). Most staff at Vet Centers have military experience.

Persian Gulf Family Support Program. Congress established an additional resource for readjustment counseling through Public Law 102-405, which directed VA to provide readjustment assistance specifically to Gulf War veterans; the department established PGFSP on October 1, 1992. VA's Social Work Service designed and implemented PGFSP based on recommendations from a task force of officials from VA, DOD, the American Red Cross, and the National Guard. The task force recommended PGFSP include: aggressive community outreach and coordination with National Guard and Reserve Units; case management of clinical services\*\* available at VAMCs, Vet Centers, community agencies, and through contract services not provided by VAMCs; staff training and education components; program evaluation; and national clinical coordination. Acknowledging the essential role families play in the readjustment process, PGFSP architects included marriage and family counseling in the program and provided these services to spouses and children of veterans.<sup>26</sup>

Congress appropriated \$10 million per year for PGFSP for a 2-year period. VA initiated the program at 36 VAMCs in the 26 states with the largest populations of formerly activated National Guard and Reserve troops. The size of the Gulf War veteran population within a VAMC region and empirical projections of the regional need for post-conflict readjustment counseling dictated staffing and funding at each site. A member from each participating VAMC's social work staff was designated PGFSP Coordinator and attended a one-week training session. Training emphasized developing effective working relationships with community agencies, establishing clinics appropriate for the client population, creating outreach goals and strategies, developing assessment and treatment goals, using therapies based on clients' needs, and providing counseling services to veterans and their families. Following training, coordinators integrated PGFSP into their VAMC infrastructures and educated hospital personnel about the evolving policies pertinent to Gulf War veterans.

Initially, the program provided services to assist veterans with readjustment difficulties. In response to concerns about emerging illnesses among Gulf War veterans, coordinators also conducted regional Gulf War illness-related outreach and enrolled clients into VA's Persian Gulf Health Registry (1-800-PGW-VETS). In conducting regional outreach, coordinators briefed National Guard and Reserve units, local veterans service organization (VSO) chapters, state veterans services offices, and grassroots family support groups. Coordinators focused on general information about PGFSP, the illnesses experienced by some Gulf War veterans, and VA's Registry. They also prepared PSAs and gave interviews to local civilian and military media.

Most coordinators appeared to develop close relationships with and personal knowledge of the veterans and active duty community within the region. They tailored appropriate outreach efforts, such as periodic newsletters, brochures distributed throughout the area, and hotline numbers for contacting the



periodic newsletters, brochures distributed throughout the area, and hotline numbers for contacting the local PGFSP. Coordinators also organized "Persian Gulf Health Days" for veterans and the general public, holding them on weekends to maximize attendance. These day-long events often offered educational seminars on illnesses, traumatic stress, and VA benefits, and brought in representatives from VSOs, state and municipal veterans affairs offices, and interested community groups. Participating veterans had the opportunity to enroll in VA's Registry and, at some sites, the Registry examinations were conducted on the weekend as well.

PGFSP coordinators at the 36 sites closely monitored the services provided under the program during its first two years. More than 2,800 outreach briefings were conducted for approximately 70,000 persons, and approximately 22,000 PGFSP outpatient visits were made by veterans and family members nationwide.<sup>166</sup> Funding for the program ended September 30, 1994. Some VAMCs continued to fund aspects of PGFSP, incorporating them into the facility's general budget. Most coordinators, however, returned to their original positions, and after the program ended, spouses and children had to contact Vet Centers to receive free counseling services.

**Transition Assistance Program.** The National Defense Authorization Act of 1991 (Public Law 101-510) authorized DOD, VA, and the Department of Labor (DOL), to provide comprehensive transition assistance for service members separating from active duty. The departments developed a Memorandum of Understanding (MOU) that established the three-day Transition Assistance Program (TAP) and assigned each department responsibilities for its implementation: DOL coordinates implementation; DOD arranges the participation of service members and provides logistical support; and VA presents veterans benefits information. TAP workshops continue to be held periodically at major U.S. military institutions in the United States and overseas, and service members are directed to attend within a 180-day period before separation.

TAP's main objective is to prevent and reduce long-term unemployment problems among veterans by educating them about goal setting, decisionmaking, labor market information, and job search techniques. The interdepartmental MOU, however, also established a high priority for informing veterans about VA benefits. Benefits briefings typically take four hours, during which benefits and application procedures are discussed; there is no standard syllabus for this discussion. It is plausible that briefings include information about DOD and VA clinical programs designed for evaluating Gulf War veterans and their families, but no evidence exists to suggest these programs are mentioned.

**Outreach to women veterans.** More than 40,000 women served in the Kuwaiti Theater of Operations (KTO). Cognizant of the increased role of women in the armed forces and the specific medical needs they could have, Congress authorized-through the Women Veterans Health Program Act of 1992 (Public Law 102-585)-new and expanded services for women veterans. Every VAMC has a Women Veterans Coordinator, who coordinates outreach and clinical services. Vet Centers also are active in providing outreach about specific VA programs for women and in building referral networks for non-VA medical and social services. RCS has a Women Veterans Working Group that has published information on specific health issues related to women veterans and guidance for outreach to this population.<sup>299</sup>

**Outreach to Latino veterans.** New Mexico, Texas, California, Arizona, Florida, and Illinois, as well as the metropolitan areas of Boston, New York City, Chicago, and Milwaukee, have large Latino veteran communities. Vet Centers and VAMCs in these regions typically have a Spanish-speaking staff member who can bridge potential language difficulties and potential cultural barriers to full utilization of the Vet Centers by the Latino veterans community. VA outreach unique to this population includes establishing relations with Latino VSOs, working with Spanish language media to publicize VA programs, and acting as a liaison with other VSOs and VA personnel for assistance in filing disability compensation claims.<sup>298</sup>

## **Military Media**

The American Forces Information Service (AFIS) and its broadcasting arm, the Armed Forces Radio and Television Service (AFRTS), comprise the bulk of DOD's internal information services. AFRTS delivers radio and television programming for service members overseas and aboard ships. AFIS oversees the

radio and television programming for service members overseas and aboard ships. AFIS oversees the European and Pacific editions of the *Stars and Stripes* newspapers and the approximately 1,100 military-funded newspapers in the United States and overseas. AFIS also has produced several media products on Gulf War veterans' health issues. Military media have undertaken the following activities related to Gulf War veterans' illnesses:

- Since early 1992 through June 1996, *Stars and Stripes* has printed 118 stories with headlines related to Gulf War veterans' health issues. The coverage appears to be similar to the civilian media, intermittently covering topics as issues evolve. Circulation is 75,000 worldwide, with readership estimates at 175,000.
- Between early 1994 and June 1996, AFRTS has broadcast 19 television and 43 radio spots on Gulf War-related health issues to an audience estimated at one million people stationed overseas and aboard ships. Although a few print stories and broadcast spots communicate how to register for either the DOD or VA clinical programs, most are general news stories on research efforts.
- AFIS also produces an *Internal Information Plan*-a collection of single-page briefs on topics of interest to military personnel, such as voter registration, drug and alcohol abuse, equal opportunity, and military benefits. The *Plan* is distributed to Public Affairs Officers at all units throughout the military, and they are encouraged to disseminate this information to service members. In 1996, a "Persian Gulf Illnesses" brief explaining DOD's Comprehensive Clinical Evaluation Program (CCEP) was added to the *Plan*, but the toll-free hotline for this service was not listed (1-800-796-9699).

## Risk Communication

The Committee first examined the government's outreach programs designed to inform veterans about their benefits. Outreach cannot stop there, however, when veterans have so many questions about the health risks of service in the Gulf. Thus, the Committee also focused attention on another aspect of the government's outreach efforts, namely risk communication.

Risk communication is a multi-step process that involves building a communication plan with specific short- and long-term objectives and using language understandable to lay persons. Risk communication also requires analyzing the affected community to determine effective methods of presenting health information, sustaining the communication process over a period of time to give the community an opportunity to increase its awareness and understanding, and establishing an open process of information exchange between the communicating agency and the affected community. Finally, any strategy must include evaluation of the performance of particular programs.<sup>23,38,48,223,258</sup>

In terms of information requirements, the scenario of Gulf War participants, who were subjected to various potential risk factors during a specific length of time, is analogous to an industrial setting, where workers are exposed to potentially hazardous agents. Additionally, the epidemiologic and clinical studies designed for Gulf War veterans are analogous to studies in which appropriate worker notification measures would be considered. Although a military conflict can be a far more complicated operation than the typical industrial setting, the risk communication experiences of several federal agencies and private institutions provide a suitable framework against which risk communication efforts for Gulf War veterans can be evaluated and compared. Thus, while risk communication in this situation is a challenge, there is a broad theoretical and experience base on which DOD and VA can draw.

Several federal agencies, including the Environmental Protection Agency (EPA) and DHHS's Agency for Toxic Substances and Disease Registry (ATSDR), have developed programs for risk communication with the public about environmental issues and health risks.<sup>30</sup> The National Institute for Occupational Safety and Health (NIOSH) conducts a function of risk communication known as worker notification, in which at-risk industrial workers participating in epidemiologic studies are informed of the results. This step provides the participants probabilistic information regarding the possibility, i.e., risk, of experiencing health effects from exposures.<sup>223</sup> The National Academy of Sciences (a private sector body that often prepares reports for the government) has published several theoretical and practical guides that emphasize the importance of risk communication in public health.<sup>173,176,177</sup>

**Federal risk communication with Gulf War veterans.** Most DOD and VA outreach efforts

**Federal risk communication with Gulf War veterans.** Most DOD and VA outreach efforts concentrate on publicizing the clinical evaluation programs and then referring participants to them. While serving a valuable function, these efforts do not fully educate veterans or sufficiently build their trust that the government's efforts to help them are comprehensive.

In addition, the target population for risk communication related to Gulf War veterans' illnesses extends beyond military service members. Members of the affected community also include family members, civilians who served in the Gulf in support roles, state veterans service officials, and national and local VSOs. Individuals who provide services to the affected community, including social workers and health care providers who come into contact with Gulf War veterans and their families and support groups, are also important risk communication targets.

Some of the departments' outreach efforts provide educational information to veterans. For example, VA publishes the *Persian Gulf Review*, a quarterly newsletter sent to those veterans who have participated in the VA Health Registry or have received other health services from a VAMC. The newsletter carries brief segments of one or two paragraphs about recently released information from reports and studies of Gulf War veterans' illnesses, developments concerning eligibility for medical services and disability compensation regulations, and common questions and answers about how to receive medical care. VA's Persian Gulf Veterans' Illnesses Internet site also provides brief, general information similar in content to the newsletter. Neither the newsletter nor the Internet site, however, provide comprehensive risk communication information about exposures or epidemiologic studies underway.

DOD's Internet site, GulfLINK, attempts to provide more salient information, such as an assessment of health effects from organophosphate exposures and reports of detections of chemical agents during the Gulf War.

However, DOD has been slow to post information, and the tone of some of the posted reports is patronizing and dismissive of veterans' concerns. DOD's growing lack of credibility-attributable largely to chemical warfare (CW) agent exposure investigations (discussed in a following section)-compounds its difficulties with effective risk communication with Gulf War veterans and others. DOD faces a complex challenge in conducting investigatory activities that require contacts with individuals who may face health risks associated with their service in the Gulf. Early efforts, such as the initial Khamisiyah telephone survey, sorely neglected the risk communication element of DOD's responsibilities.

Effective risk communication requires a dialogue-a two-way flow of information, opinions, and perceptions.<sup>258</sup> DOD and VA have not established clear pathways for veterans to provide feedback about clinical programs and/or about concerns regarding exposures; nor have they canvassed the Gulf War veterans' community regarding better methods of communication. It appears the only way in which a veteran could provide feedback would be through contact with the clinical personnel at local VAMCs or military hospitals. This, however, does not appear to be a likely route for transmitting concerns to decisionmakers. VA does conduct periodic interactive video teleconference sessions on Gulf War health topics for clinical and social work staff, but this format is designed for staff education, not as a formal, publicized mechanism of interaction with veterans and other members of the public.

Likewise, the telephone hotlines also are designed for a one-way flow of information. VA and DOD health care hotlines are for referrals only. DOD's Incident Reporting Line (1-800-472-6719) and Khamisiyah investigation telephone survey have been used to collect-not disseminate-information. For example, there often has been no follow-up response from DOD to Incident Line callers about reported incidents, nor has there been adequate disclosure through any existing outreach methods concerning the overall progress of the investigation into CBW agent incidents.

Another opportunity for DOD and VA to interact with members of the target community is in the design and execution of epidemiologic studies. In the *Interim Report*, this Committee found that public advisory committees might improve communications with veterans who are asked to participate in epidemiologic studies, and we recommended DOD, DHHS, and VA urge their principal investigators to use public advisory committees in epidemiologic studies of Gulf War veterans' health issues. Departmental response to this recommendation has been half-hearted, at best.

DOD and VA need to emphasize feedback procedures in their outreach programs. Creating a dialogue with a disparate veterans population is central to effective risk communication and warrants increased attention from the departments.

**Role of veterans service organizations.** There appears to be a role for VSOs in developing and implementing risk communication strategies for Gulf War veterans, since many VSOs have extensive networks in place throughout the country. VSOs represent veterans in social and legislative matters at the national, state, and local levels. Many VSOs-including the American Legion, Veterans of Foreign Wars, and Vietnam Veterans of America-have been chartered by Congress. VSOs already have an established working relationship with the VA in many areas, including working with Vet Centers on readjustment issues, sitting on the Persian Gulf Expert Scientific Committee, and providing advocates for the disability compensation claims process. Currently, some VSOs are working on behalf of Gulf War veterans, mostly with assistance in the disability compensation claims process. Several VSOs recently have emerged in various regions of the country specifically to serve Gulf War veterans. The interests of many of these groups are represented in Washington, DC, by the National Gulf War Resource Center, which was organized in 1995.

An example of VSOs implementing useful risk communication is the *Self Help Guide for Veterans of the Gulf War*,<sup>178</sup> developed by the National Veterans Legal Services Program (NVLSP) and distributed by the American Legion. The *Guide* provides an overview of the nature of Gulf War veterans' illnesses, explains some health risk factors associated with Gulf War service, and describes eligibility requirements for receiving VA medical benefits. In a different vein, an example of VSOs as a credible resource for veterans is their work in the complicated disability compensation process. Concerned about the 95 percent denial rate for undiagnosed illness claims, the American Legion developed an undiagnosed illnesses application addendum for the VA disability compensation claims process. When completed, the addendum provides a comprehensive description of the veterans' clinical profile and military operational history, which are important factors in the claims process.

The issue of risk communication will only increase in relevancy as studies with specific findings about the nature of Gulf War veterans' illnesses are released. These findings might be unclear to the veterans and, indeed, some conclusions could offer a message some veterans would prefer be different. In such cases, trust, credibility, interaction, and community involvement are key to successful risk communication-but it is not clear whether DOD or VA will have personnel in place to conduct effective risk communication when findings from various reports are ready for dissemination. VA has Persian Gulf Coordinators assigned to each medical center, but these personnel have other responsibilities and typically are more involved with clinical case management.

To date, DOD and VA have not devised a plan with specific objectives for effective health risk communication.<sup>216,217</sup> There are many messages to exchange in a health risk communication process, especially one as complicated as the possible health consequences of service in the Gulf War. A process that adequately addresses risk communication in this area would by necessity involve the following: educating members of the community about the certainties and uncertainties of the health risks of various exposures, using the media as a conduit of information, having frequent and sustained contact with the affected community, and validating the information and the source of information with appropriate external reviews.

### **Findings Regarding Outreach**

Based on its analysis of the government's programs for outreach concerning services available to Gulf War veterans and for communicating with veterans about the risks of Gulf War service, the Committee makes the following findings:

- In their geographic areas, Vet Center staffs have established working relationships with the veterans community, veterans service organizations, local municipal and state veterans liaison offices, in-region Guard and Reserve units, community social services organizations, local VA medical center personnel, and military establishments. These relationships enable Vet Centers to provide education and outreach to local communities about issues and clinical programs

provide education and outreach to local communities about issues and clinical programs concerning Gulf War veterans, and a significant number of Gulf War veterans use their services.

- The outreach initiative of VA's Persian Gulf Family Support Program was an effective method of communicating information about Gulf War veterans illnesses-in particular the established government clinical programs-to veterans, Reservists, National Guard members, and local communities. The program used trained, knowledgeable personnel in the field to establish a communication network with the community and deliver specific information directly to Gulf War veterans.
- Ninety percent of separating active duty service members attend Transition Assistance Program (TAP) workshop briefings conducted jointly by DOD, VA, and DOL. VA benefits briefings during the TAP workshop could be an effective method of outreach about DOD and VA programs for evaluating Gulf War veterans illnesses, yet there is no evidence their clinical programs receive mention.
- Through the initiatives of the Women Veterans Health Programs, VA has implemented a range of efforts to inform women veterans about available health services.
- In regions with significant Latino populations, Vet Centers and VA medical centers deliver bilingual, cross cultural outreach and services.
- While newspaper articles and television and radio broadcasts disseminated by DOD's American Forces Information Service provide adequate media coverage of Gulf War illnesses-related issues, few of the media products perform the outreach functions of publicizing government-sponsored Gulf War veterans clinical programs and methods of referral into them.
- DOD's *1996 Internal Information Plan-Persian Gulf Illnesses* describes its Comprehensive Clinical Evaluation Program, yet fails to provide the most basic information on how to register for it.
- Effective risk communication is essential to the government's credibility on Gulf War veterans' illnesses, but DOD and VA have not seriously attempted to educate veterans about health effects of service in the Gulf War or to establish a dialogue concerning research programs relevant to veterans' concerns.
- Several federal agencies have developed, tested, and validated techniques for health risk communication that could be adopted by DOD and VA.

The Committee's recommendations for governmental actions based on these findings appear on page 50.

## MEDICAL AND CLINICAL ISSUES

In our *Interim Report*, the Committee focused on medical treatment issues that surfaced during the deployment and demobilization of troops. We found DOD's policies and procedures were not adequate to prevent some service members with preexisting conditions from being deployed or to identify health problems extant at the time of demobilization; we noted these conditions could have contributed to some current health concerns.

The Committee also found that DOD and the Food and Drug Administration (FDA) deliberated carefully before enabling, through rulemaking, DOD to require troops to take pyridostigmine bromide (PB) and botulinum toxoid (BT) vaccine as pretreatments for possible CBW agents without FDA approval of the products for that purpose.<sup>304</sup> We were concerned that FDA had failed, in the five years since the Gulf War, to devise better long-term methods governing military use of drugs and vaccines for CBW defense. We also found DOD's inability to produce records of who received PB or BT indicative of much need for wholesale improvement in the government's performance on medical recordkeeping during military engagements. As a result, our *Interim Report* made the following recommendations:

- DOD should regularly review and update the policies and procedures that govern the pre-, during, and postdeployment medical assessment of the Ready Reserve to ensure they are current and adequate.
- DOD should establish a quality assurance program to ensure compliance with pre-, during, and postdeployment medical assessment policies.
- Prior to any deployment, DOD should undertake a thorough health assessment of a large sample of troops to enable better postdeployment medical epidemiology. Medical surveillance should be standardized for a core set of tests across all services, including timely postdeployment followup.

- standardized for a core set of tests across all services, including timely postdeployment followup.
- Given that FDA's Interim Final Rule permitting waiver of informed consent for use of unapproved products in a military exigency is still in effect, DOD should develop enhanced orientation and training procedures to alert service personnel they may be required to take drugs or vaccines not fully approved by FDA if a conflict presents a serious threat of chemical and biological warfare.
- If FDA decides to reissue the Interim Final Rule as final, it should first issue a Notice of Proposed Rule Making. Among the areas that specifically should be revisited are: adequacy of disclosure to service personnel; adequacy of recordkeeping; long-term followup of individuals who receive investigational products; review by an institutional review board outside of DOD; and additional procedures to enhance understanding, oversight, and accountability.
- DOD should assign a high priority to dealing with the problem of lost or missing medical records. A computerized central database is important. Specialized databases must be compatible with the central database. Attention should be directed toward developing a mechanism for computerizing medical data (including classified information, if and when it is needed) in the field. DOD and VA should adopt standardized recordkeeping to ensure continuity.

This section of the *Final Report* includes the Committee's assessment of the government's response to our *Interim Report* recommendations and includes additional findings and recommendations concerning medical and clinical issues.

### **DOD's Response**

DOD has been responsive to Committee recommendations about medical treatment policies governing pre-, during, and postdeployment of U.S. troops. DOD has not been responsive, however, to the Committee's recommendation that prior to any deployment, DOD should undertake a thorough health evaluation of a large sample of troops to enable better postdeployment medical epidemiology.

One of the overriding difficulties of research on Gulf War veterans' illnesses is the absence of baseline data-on health and on exposure to environmental hazards. DOD testified it has improved its approach to gathering such data and has incorporated new policies and procedures in its medical surveillance and environmental monitoring programs.<sup>40,213</sup> Although DOD has introduced these techniques in the Bosnia peacekeeping mission, they have not been tested in a large-scale conflict. Laying the groundwork for post-conflict medical surveillance could be perceived by some as a low priority in a war-fighting environment. There is no evidence that DOD has identified a standardized set of tests or physical examination procedures and applied them to a large sample of troops across all services to ensure that medical epidemiology can be conducted in the aftermath of an operation.

With regard to using investigational new drugs, DOD has made the effort in Bosnia to provide information about the risks of tick borne encephalitis (TBE) and the investigational TBE vaccine being administered, with informed consent, to U.S. troops in that region. However, DOD has made no specific response to the Committee's recommendation on educating troops about investigational pharmaceuticals-i.e., given that the Interim Final Rule is still in effect, DOD should develop enhanced orientation and training procedures to alert service personnel they could be required to take investigational drugs or vaccines not fully approved by FDA if a conflict presents a serious threat of exposure to CBW agents.

With respect to our *Interim Report* recommendation concerning medical recordkeeping, the Committee observes that DOD has made progress in working toward improving medical recordkeeping in-theater and stateside. However, increased commitment from DOD's Joint Chiefs of Staff and Commanders in Chief is essential for increasing the priority of this effort.

### **FDA's Response**

FDA has testified that it is now considering the Interim Final Rule in conjunction with guidelines for CBW agent prophylaxis approval; it is also considering how it should address military and civilian use.<sup>132</sup> The Committee remains concerned, however, about the amount of time FDA is taking to move forward with opening up the Interim Final Rule-which was issued almost six years ago-for public comment.

comment.

## Issues New to This Report

To complete its work on medical and clinical issues, the Committee assessed whether Gulf War veterans currently receive access to quality medical care under programs established by the government for their care. We specifically examined the availability of reproductive health care because of the high degree of concern expressed by Gulf War veterans and their families in this regard. Finally, the historically important role of post-conflict stress reactions on the health of veterans<sup>132</sup> led us to give particular scrutiny to this issue.

## Access to Health Care

Beginning with our first meeting in August 1995, the Committee heard frequent public comment about the difficulty of gaining access to health care in VAMCs and, to a lesser degree, DOD medical facilities. Inadequate information, delays in scheduling appointments, insensitive personnel, and inadequate followup topped the list of complaints. The Committee decided a series of site visits and interviews could help inform our deliberations in determining whether problems with access to care persist or largely preceded establishment of VA's Registry and DOD's CCEP. Facilities for site visits were selected to vary geographically and represent initial evaluation sites (Phases I and II) and referral centers. Between November 1995 and February 1996, Committee members and staff visited the following sites:

- VA Medical Center, Washington, DC (Referral Center; Phases I and II)
- VA Medical Center, Durham, NC (Phases I and II)
- VA Medical Center, Houston, TX (Referral Center; Phases I and II)
- VA Medical Center, Indianapolis, IN (Phases I and II)
- Naval Medical Center, San Diego, CA (Referral Center; Phases I and II)
- Walter Reed Army Medical Center, Washington, DC (Specialized Care Center; Phases I and II)
- Eglin Air Force Base, Ft. Walton Beach, FL (Phase I)
- University of Louisville Medical Center, Louisville, KY (CCEP contractor for Fort Knox; Phases I and II)

Site visits included interviews with medical facilities' commanders or chiefs of staff, Registry or CCEP coordinators, medical and nonmedical staff assigned to the program, and veterans undergoing evaluation. Committee members and staff also took walking tours of dedicated facilities and reviewed randomly selected medical records of Gulf War veterans.

**Clinical evaluation programs.** In August 1992, VA established its Registry for veterans who had returned to civilian life. DOD established the CCEP in June 1994 for Gulf War veterans remaining on active duty. These clinical programs are available, free of charge, to any Gulf War veteran. Both the Registry and CCEP are treatment programs, not research protocols, but the data have been used to generate research hypotheses.

VA and DOD maintain databases for their clinical care programs. The databases for the Registry and CCEP can generate information useful for patient care—both for diagnosis and for risk communication.

**Quality of care.** The VA Registry originally consisted of a medical history, a thorough physical examination, and basic laboratory tests. If indicated, participants received specialty consultations as Phase II of the evaluation. While the Phase I and Phase II examinations essentially were equivalent to a good internal medicine evaluation, initially no uniform protocol existed for the assessment of participants in the Registry. As the program developed, VA established requirements for certain specialty examinations for all participants and standard questions regarding possible exposures while in the Gulf. By early 1994, a uniform assessment protocol, which is in use today, was in place systemwide. As of October 1996, approximately 62,000 Gulf War veterans had completed physical examinations in VA's Registry program. The most frequently cited symptoms, which have remained consistent over time, include fatigue, headache, skin rash, muscle and joint pains, and memory loss. The majority of participants receive a diagnosis, but approximately 20 percent of veterans who describe symptoms during the physical examination(s) complete the Phase I and/or Phase II examinations without receiving



during the physical examination(s) complete the Phase I and/or Phase II examinations without receiving a diagnosis.

DOD uses the same examination protocol for its CCEP.\*\*\* Initially, any CCEP participant who wanted a Phase II evaluation was given one without a specific referral from his or her physician. DOD modified this policy in January 1995 and now requires a physician referral for Phase II. As of October 1996, approximately 34,000 individuals had requested physical examinations in the CCEP. DOD has published information derived from more than 18,000 CCEP examinations,<sup>277</sup> and the findings are similar to those for VA's Registry. The most frequently cited symptoms have been fatigue, headache, skin rash, joint pain, and memory loss. All CCEP participants receive a diagnosis, but approximately 18 percent of the primary diagnoses fall into the category "ill-defined symptoms and signs," with no specified cause.

VA designated medical centers in Washington, DC, Houston, TX, Los Angeles, CA, and Birmingham, AL, as Referral Centers for evaluating veterans who have unexplained illnesses after the Phase I and II examinations. DOD established a Specialized Care Center at Walter Reed Army Medical Center for the evaluation, treatment, and rehabilitation of Gulf War service members with chronic debilitating symptoms.

**Appointment scheduling.** VA offers the Phase I examination at any VA medical facility; Phase II examinations are performed at any secondary or tertiary care facility. Phase I evaluations through the CCEP can be done at any military treatment facility. DOD's Phase II evaluations are conducted at one of the 14 tertiary care medical facilities (one for each of the 13 geographic regions except region 6, which has two) with the required specialty staff.

When VA's Registry began in 1992, veterans often encountered significant delays throughout the system in scheduling appointments-chiefly because of the large number of veterans requesting examination, the newness of the program, and the need to reassign space and personnel within facilities. Experience gained over time, the development of streamlined procedures, and the decreasing rate of veterans entering the Registry largely have eliminated major delays in scheduling an initial examination. Delays-usually less than 30 days-can occur in scheduling Phase II evaluations depending on the availability of specialists.<sup>4</sup> Evaluations at one of VA's four Referral Centers entail administrative delays associated with medical records preparation and consultations with referring physicians. Referral Centers follow a more rigorous protocol requiring a greater commitment of time and specialty resources and limits the number of participants at any one time. Delays of three months or more are not uncommon.

The Committee heard fewer complaints about initial appointment scheduling in the CCEP program and found that delays in scheduling

Phase II referrals seldom exceed two weeks. The Specialized Care Center at Walter Reed, a rigorous 30-day program, requires advance scheduling and consultation, but at the time of our visit we heard of no delays.

**Personnel and space.** By the time Committee members and staff initiated our site visits in November 1995, all facilities had a designated Gulf War Veterans Program coordinator and support staff who were responsible for scheduling and conducting the evaluations. Committee and staff interviewed these individuals and found them knowledgeable about the Registry or CCEP programs and their individual responsibilities. Staffing at the facilities we visited is currently sufficient to conduct Phase I and Phase II evaluations, although the variability of available specialists to conduct portions of the Phase II evaluation causes some delays in a few of the facilities visited.

The large numbers of service members who registered in the CCEP initially threatened to overwhelm the resources of the Internal Medicine Department at Fort Knox. A significant backlog of participants awaiting Phase I evaluation existed in February 1995, when DOD mandated that all requested workups nationally would be completed by April 22, 1995. Because Fort Knox had only three internists at the time, CCEP registrants consumed all of their clinic time. In response, two physicians from Wright-Patterson Air Force Base were detailed to Fort Knox to assist with the evaluations. Contract



Wright-Patterson Air Force Base were detailed to Fort Knox to assist with the evaluations. Contract arrangements also were made with the University of Louisville to conduct Phase I evaluations from Fort Knox beginning July 26, 1995. Participants requiring Phase II evaluations are still referred to the U.S. Air Force Hospital at Wright-Patterson Air Force Base, Dayton, OH, but Phase II evaluations now also are conducted at the University of Louisville.

The Fort Knox example of clinic overload was the most extreme example of clinical disruption at facilities visited by the Committee. Eligible beneficiaries who were not on active duty, other than Gulf War veterans, who requested appointments at the Fort Knox Internal Medicine Clinic in the spring of 1995 were referred to civilian care under DOD's Civilian Health and Medical Program of the Uniformed Services (CHAMPUS). All other facilities we visited maintained they had extended hours and worked harder to avoid interfering with the usual hospital routine. In our conversations with clinic and program staff, they noted there had been some disruption in the early part of both clinical care programs, but that the problems had not been severe. The most frequently mentioned effect was the pressure on clinical and program staff to complete the evaluations in a timely manner-particularly at the DOD facilities during January to May 1995.

Most facilities did not designate a separate clinic space for Phase I evaluations, seeking to mainstream participants as much as possible and reduce the possibility of symptom sharing. Some facilities (e.g., VAMC, Durham, NC), have set aside specific clinic hours for the Gulf War evaluations and report no evidence of symptom sharing among their group of veterans. With the significant reduction in numbers of Gulf War veterans seeking evaluation, all clinical spaces we visited are more than adequate to handle current demand. As was noted earlier, however, the extent to which this remains true is unclear, given recent heightened media attention to Gulf War illnesses.

**Staff education.** In contrast to the extensive knowledge of staff assigned directly to Gulf War-related programs, the knowledge level of staff not specifically assigned to the Registry or CCEP at both VA and DOD medical facilities was problematic. For example, the existence of the CCEP was largely unknown among staff at the VA facilities we visited. Moreover, it was astonishing in one instance to find that a physician treating Gulf War veterans in his VA post-traumatic stress disorder (PTSD) research was unaware of the VA Registry. There have been scattered Continuing Medical Education (CME) programs for DOD and VA medical facility staff about the government's Gulf War programs, but these are intermittent, usually limited to a single department, and not well attended.

At the time of the Committee's site visits, some staff at the VA medical facilities complained they were receiving less information about the program from VA Central Office than they felt they needed. While recognizing the educational outreach concerning the Registry program undertaken by the Central Office, they wanted more information about results of the Registry evaluations and about research being undertaken. Staff at DOD's facilities expressed general satisfaction with the feedback they received.

**Staff attitudes.** The Committee heard public comment at each meeting citing insensitive attitudes on the part of staff at both DOD and VA medical facilities. Frequently, these reports by veterans and their families centered on a dismissive or cynical approach to the veterans' problems-i.e., the message received was that problems were "not real" or "all in your head." Veterans who sought care after the Gulf War but before the establishment of the Registry and CCEP appeared to suffer most from this treatment.

In our interviews with staff at the eight medical facilities, we encountered a range of views about the problems being experienced and reported by Gulf War veterans. Some VA and DOD staff members expressed the belief that the thorough, structured evaluations in the Registry and CCEP were overkill and were exacerbating any problems that existed through the reinforcement of a sick role. Others felt constrained by the rigidity of the evaluation protocol-that it did not allow for flexibility of clinical judgment-and felt this was "not the way I would practice medicine." No VA or DOD staff members interviewed stated they believed that these veterans were not actually ill.

Patient satisfaction surveys carried out at several of these facilities find a greater than 80 percent approval rate by all patients, including Gulf War veterans.

**Adequacy of medical records.** Medical records of Registry and CCEP participants at each facility are

**Adequacy of medical records.** Medical records of Registry and CCEP participants at each facility are maintained separately from other patient records, and there is a final, common pathway for determining when the records are complete and ready to be certified by a physician's signature. When completed, patient data are reported to either VA Central Office or DOD Health Affairs.

Committee staff reviewed a ten percent sample of randomly selected medical records of Gulf War veterans at each facility visited. Records were reviewed for completeness, adherence to protocol and, particularly, documentation of diagnoses by specialty consultation and/or laboratory reports.

In its reviews, Committee staff found only minor deviations from completeness and adherence to protocol. In each instance where Committee staff noted missing documentation for a discharge diagnosis, facility staff was able to locate the necessary documentation. It appears that, overall, medical records for these veterans are complete.

**Follow-up treatment.** After completing a Registry or CCEP examination, Gulf War veterans are, in most instances, returned to their local medical facility for follow-up care. Despite the general medical adequacy of the VA and DOD evaluation programs, follow-up treatment-particularly where mental health visits are involved-are problematic. Staffing constraints often result in long delays in scheduling appointments in some specialties. Psychiatric staffing is particularly overloaded at some sites.

Many Registry and CCEP participants are receiving follow-up care from a number of physicians, both federal and private sector. No single case manager is guiding their care. The absence of a case manager can lead to confusion and, in some cases, over medication of patients.

Follow-up treatment of active duty veterans also is made more difficult by command resistance to granting the necessary time off to maintain an adequate treatment program. This is true for all chronic illnesses, but especially so for psychological diagnoses.

### **Reproductive Health Services**

The birth of a child with a disabling, disfiguring, or lethal condition is devastating to the parents and family of that child. Likewise, the inability to produce a wanted child is usually unexpected and almost always anguishing. Most people want to know why this has happened to them and their family. Understanding what caused, or at least did not cause, the problem can often bring relief.

**Care provided to active duty service members.** When a couple experiencing infertility, a woman in a high risk pregnancy, or an infant with a birth defect enters the military health care system, a comprehensive range of services-from primary to tertiary care-are available. Beneficiaries who experience fertility problems can use their benefits to obtain a variety of reproductive health services, including infertility testing and treatment. A

child with special health needs receives a full range of medical and related health care benefits to the full extent of his or her disability. In addition, a child with a disability and incapable of self-support remains eligible for care in the military's medical services system as a family member of an active duty member or retiree, even after the age of majority.<sup>256</sup>

**Care provided to veterans who have separated from service.** Reproductive-related medical care and counseling for individuals no longer on active duty stands in stark contrast to coverage for active duty service members. With the exception of children with spina bifida born to in-country Vietnam veterans, VA currently lacks the authority to provide benefits or services on the basis of adverse health effects in children-even if the effects are shown to result from their parents' service experience. Evaluation and treatment for infertility of veterans is limited to a small number of situations in which the cause of the infertility could have been detected and treated while on active duty (e.g., diabetes in women or service-related spinal cord injury in men). In general, obstetrical services are not offered to female veterans through the VA medical system-except for care relating to a pregnancy that is complicated or in which the risks of complication are increased by a service-connected condition. VA has no policies in place to systematically address the concerns of Gulf War veterans regarding reproductive health.

### **Prevention of Combat-related Stress Reactions**

## **Prevention of Combat-related Stress Reactions**

Building on research on veterans of Korea, Vietnam, and the Gulf, DOD has undertaken an ambitious program to proactively address combat-related stress. The U.S. Army, through the Department of Military Psychiatry, Walter Reed Army Institute of Research, has instituted a Human Dimensions Research Program. One important observation has been that strong leadership and unit cohesion are firmly associated with reduced severity of stress reactions. U.S. Army doctrine embraces this finding and emphasizes it in its field manuals.

Combat Stress Control Detachments have been established (six in the Active Army and nine in the Reserve), each consisting of a psychiatrist, psychologist, social worker, psychiatric nurse, clinical nurse specialist, occupational therapist, and two enlisted technicians. These detachments provide predeployment briefings that address all known health hazards, including stress, that individuals might face during the deployment. During deployment, members of the detachments are instructed to be highly visible to the commanders and troops. One of these detachments has been deployed to Bosnia.

Combat Stress Control Detachments provide briefings for units newly arrived, provide special training in stress management techniques and, most important, they conduct unit survey interviews throughout the deployment. Unit interviews are a systematic tool for gathering information from the troops and then reporting to the command what is troubling the troops and how well leadership is functioning. When critical events occur, the trained individuals in the detachments debrief personnel directly involved, provide consultation to the leaders and chaplains, and provide any special education that could be needed. At the end of a deployment, all units, including those in which no critical events occurred, receive an end-of-tour debriefing by the Combat Stress Control Detachment. Those units exposed to particularly critical events receive special attention to ensure that unit members have a chance to talk through events and reach appropriate closure prior to returning home.

Follow-up plans for the Bosnia deployment include studies that will take place six months after veterans return. Plans also are under discussion to continue to follow the same individuals, with appropriate informed consent, over the long term.

Tertiary prevention programs, such as Vet Centers within the VA medical system, also can help minimize stress-related conditions before they become too severe. As noted earlier in this chapter, Vet Centers were established after the Vietnam War to provide support for Vietnam veterans with PTSD and other mental health concerns. There are 205 centers located around the United States, and since 1991, more than 66,000 Gulf War veterans in over 210,000 visits have availed themselves of these centers.<sup>8</sup>

## **Findings Regarding Medical and Clinical Issues**

Based on the government's response to the recommendations in the Committee's *Interim Report* and additional interviews, site visits, briefings, and testimony, the Committee makes the following findings regarding medical and clinical issues:

- DOD has not been responsive to the Committee's recommendation that prior to any deployment, DOD should undertake a thorough health evaluation, including a core set of diagnostics, of a large sample of troops to enable better postdeployment medical epidemiology along with timely postdeployment followup.
- FDA is moving toward soliciting public comment on alternatives to the Interim Final Rule related to permitting a waiver of informed consent for use of investigational products during military exigencies. The Committee remains seriously concerned about the amount of time—currently approaching six years—FDA is taking to open the process to public comment.
- DOD has not been responsive to the Committee's recommendation that it should routinely inform recruits and troops, through orientation and training procedures, about the possible use of investigational drugs or vaccines for chemical and biological warfare agent purposes. DOD's lack of response in this highly sensitive area contributes to the perception of many that U.S.
- troops were inappropriately subjected to investigational drugs or vaccines during the Gulf War.
- DOD has made progress in improving medical recordkeeping in-theater and stateside, but increased and sustained commitment from DOD's Joint Chiefs of Staff and Commanders in Chief

increased and sustained commitment from DOD's Joint Chiefs of Staff and Commanders in Chief will be necessary for current prototypes and plans to be fully and successfully integrated and implemented.

- Clinical staff not directly involved in VA's Registry and DOD's CCEP are not well informed about the programs.
- Follow-up treatment, particularly when mental health visits are involved, is problematic within both VA and DOD. Staffing constraints occasion long delays in scheduling appointments. Commanders are sometimes resistant to making sufficient time off available for active duty veterans to maintain an adequate treatment program.
- Reproductive health care benefits available to active duty service members and their families through the Military Health Services System are comprehensive and the standard of care.
- Reproductive health concerns are addressed on a case-by-case basis within DOD, and VA has extremely limited authority to treat such concerns at all. Neither DOD nor VA have widespread or systematic policies in place to address the concerns and questions of Gulf War veterans concerning reproductive health.
- DOD and VA have implemented innovative programs to help veterans cope with combat-related stress.

The Committee's recommendations for governmental actions based on these appear findings on page 52 of the printed version of the *Final Report*.

## RESEARCH

In our *Interim Report*, the Committee found most of the major epidemiologic studies sponsored by DOD, VA, and DHHS to be well designed and appropriate to determine if Gulf War veterans have mortality, symptoms, or diseases that could be attributable to service in the Gulf War. We were concerned, however, that inadequate response to scientific peer review, disregard for the importance of allocating scarce research dollars to the best designed studies, and inattention to the need to communicate effectively with veteran participants were undermining the effectiveness of the government's research efforts. Finally, we found that the lack of data about exposure to various risk factors was hampering ongoing research. The Committee's *Interim Report* included the following recommendations based on our preliminary analysis of the government's research programs:

- All epidemiologic studies aimed at Gulf War veterans' health issues should incorporate external scientific review and ongoing interaction with appropriate outside experts throughout the study process, from study design through analysis of results.
- The Persian Gulf Veterans Coordinating Board should play an active role in allocating the limited resources available for research on Gulf War veterans' illnesses. The Research Working Group of the Coordinating Board should monitor the findings and recommendations of scientific peer review committees. If scientific reviews draw into question the usefulness of particular studies to the overall research strategy, the Research Working Group should, via the Coordinating Board, recommend appropriate actions to the Secretaries of the three departments involved.
- DOD, DHHS, and VA should recommend their principal investigators use public advisory committees in designing and executing epidemiologic studies of Gulf War veterans' illnesses.
- For those questions that are common to different epidemiologic surveys, coordination between principal investigators and survey design experts should take place to arrive at common wording. The Persian Gulf Veterans Coordinating Board's Research Working Group should take responsibility for this coordination.
- The Persian Gulf Registry of Unit Locations should be made available to qualified government and private researchers as quickly as possible, within the constraints of confidentiality.
- DOD should make reasonable and practical efforts to collect and record better troop exposure data during future conflicts and to make those data available as quickly as possible to health care researchers.

The following section of the *Final Report* includes the Committee's assessment of the government's response to our *Interim Report* recommendations and includes additional findings and recommendations concerning research.

## Departmental Responses

The government has been responsive to these recommendations in general, but the Committee notes continuing problems in two areas: the use of public advisory panels for epidemiologic studies and the utility of the Persian Gulf Registry of Unit Locations.

**Public advisory panels.** While VA and DOD have encouraged their principal investigators to convene and consult scientific advisory committees, they have not taken serious steps to encourage the formation and use of public advisory committees. Although public advisory committees will be recommended for epidemiologic studies recently funded by DOD and VA, their use is given low priority by program administrators. The Committee believes this practice is unfortunate because, as is evidenced by the experience of the Centers for Disease Control and Prevention (CDC), public advisory committees can greatly facilitate incorporation of veterans' concerns into study design, dissemination of results, and risk communication.

**Persian Gulf Registry of Unit Locations.** DOD has made its congressionally mandated Persian Gulf Registry of Unit Locations available to govern

ment and private researchers, but the database lacks the precision and detail necessary to be an effective tool in the investigation of exposure incidents. More to the point, the unit locator database has failed in its application to the single CW agent incident investigated by DOD in any detail to date-i.e., Bunker 73 and the pit at Khamisiyah.

In its Khamisiyah investigation, the Persian Gulf Veterans' Illnesses Investigation Team (PGIT) has not relied on reports provided from the database because the assumption on which the database is premised-that individuals remain with their units-was the exception rather than the rule in the theater of operations. Instead, PGIT went to the operational records and has engaged in a series of interviews to try to piece together a more accurate picture of troop locations. PGIT found that, in the field, individuals performed duties while assigned to discrete groups that might or might not be represented by one of the database's unit identification codes. In addition, records of unit locations, which still are maintained manually, were sometimes incomplete and/or inaccurate. For these reasons, the Committee concludes the unit locator has not proved to be a valuable tool for investigating exposure incidents. The effort has been no more successful than the effort to compile similar information following the Vietnam War to examine possible exposures to Agent Orange. Regrettably, DOD raised expectations about the potential utility of the database far beyond reason, given the data available to developers of the computer database. Better data-whether acquired through rigorously enforced manual methods or new technologies such as devices that interact with the Global Positioning Satellite system-should receive higher priority from DOD.

## Issues New to This Report

To complete its evaluation of federally funded research on Gulf War veterans' illnesses, the Committee assessed whether the government's research portfolio is well managed and whether federally funded research addresses an appropriate range of questions relevant to Gulf War veterans' illnesses.

## Management of the Federally Funded Research Portfolio

The Committee focused on four areas related to the government's management of federally funded research in Gulf War veterans' illnesses: coordination, research centers, prioritization, and external review.

**Coordination.** The Persian Gulf Veterans Coordinating Board (Coordinating Board) manages the government's Gulf War veterans' health research. Established in January 1994, the interagency Coordinating Board is comprised of the Secretaries of Defense, Health and Human Services, and Veterans Affairs, and its Research Working Group (RWG) has primary responsibility for research related to possible health consequences of Gulf War service. The RWG's tasks include coordinating studies to avoid unnecessary duplication, ensuring a focus on high priority research, assessing the status

studies to avoid unnecessary duplication, ensuring a focus on high priority research, assessing the status and direction of federally funded research, identifying possible gaps in understanding

Gulf War veterans' health issues, recommending future research directions, and generating periodic reports to Congress. Oversight of individual projects within the government's portfolio rests within the funding agency. Each department has its own established funding and management procedures for its intra- and extramural research programs.

DOD and VA have historical roles in research on the health of active duty service members and veterans, and they take the lead in the RWG partnership. DHHS has historical strengths in public health (e.g., CDC) that are brought to bear in this effort. However, except for the National Institute of Environmental Health Sciences, DHHS's many basic biomedical research intramural activities and extramural projects that could contribute substantial expertise to Gulf War health issues are peripherally involved in RWG's activities, if at all.

**Research centers.** The government has developed some innovative approaches to address Gulf War veterans' health research. For example, in October 1994 it launched three Environmental Hazards Centers in Portland, OR, East Orange, NJ, and Boston, MA. At the outset, the goal was to bring together teams of highly qualified researchers with relevant expertise in veterans' health issues. The centers are joint VA-university endeavors—each funded at approximately \$500,000 per year for five years—and they support interdisciplinary collaborations and interactions between VA and academic scientists.

Testimony before the Committee and staff site visits indicate each of the centers brings a different array of expertise to the broad set of questions relevant to Gulf War veterans' illnesses. To date, the centers have produced some well-designed studies. Moreover, the range and depth of research at the centers suggests these studies will provide useful contributions to understanding Gulf War-specific health concerns, as well as those that could arise with future conflicts.

The possibility that reproductive health problems and birth defects might be tied to service in the Gulf War is of special concern to many veterans and their families. VA solicited applications in May 1996 to establish a research center for epidemiologic, clinical, and basic science studies of environmental hazards and their effects on reproductive and developmental outcomes. In November 1996, the VAMC in Louisville, KY was selected as the site for this multidisciplinary center. The center may collaborate with federal and state agencies that collect birth outcome data and that have experience with relevant chemical exposures. The center is not specific to reproductive issues related to Gulf War veterans, but has the broader mission of analyzing reproductive health research for all veterans.

**Prioritization.** In addition to developing the center-based approach, RWG also established priorities for federally funded research on Gulf War veterans' illnesses. Research priorities were published first in August 1995.<sup>294</sup> These evolved over the next few months, and in response to questions from the Committee in May 1996, the RWG identified and ranked priority research areas.<sup>149</sup> In order of priority, these were:

- reproductive health, including male contribution to adverse reproductive health outcomes;
- mortality follow-up studies;
- stress;
- illnesses in non-U.S. coalition forces and indigenous populations;
- toxicology of pesticides, CW agents, and PB (alone and in combination with other factors);
- toxicology of depleted uranium (DU), solvents, and fuels; and
- infectious diseases, especially leishmaniasis and BW agents.

The Committee commends the effort to set priorities and notes these priorities were applied to the most recent round of the government's research awards. We have identified a more narrow range of priorities for research on Gulf War veterans' health concerns. Specifically, the Committee views the principal uncertainties about Gulf War veterans' illnesses as: the long-term health effects from low-level exposure to CW nerve agents, the long-term health effects from stress, the long-term health effects from exposure to known carcinogenic and mutagenic compounds (such as mustard agent), and the long-term health effects of interactions between PB and other agents. We note that RWG's new priorities, published in

effects of interactions between PB and other agents. We note that RWG's new priorities, published in November 1996, emphasize clinical investigations of service members who may have been exposed to CW agents.<sup>295</sup> The Committee agrees with the RWG that research on other (former) priority areas could be important for future conflicts.

**External review.** The departments have incorporated external scientific merit review into their research selection processes. Proposals for funding through DOD's fiscal year 1995 Broad Agency Announcement (BAA) were reviewed for scientific merit and relevancy by the American Institute of Biological Sciences.

To maximize the validity and interpretability of study findings, and as recommended in the Committee's *Interim Report*, external scientific review has been incorporated for most studies. External scientific review for smaller studies supported by indirect cost accounts is more variable.

Each agency of the RWG has its own standing advisory committees charged with overseeing research generally, including VA's Persian Gulf Expert Scientific Committee, the Armed Forces Epidemiology Board, the Defense Science Board (DSB), and study groups at the National Institutes of Health (NIH). None of these groups, however, has interagency appointments and/or responsibilities. Moreover, none is charged specifically with overseeing post-conflict health research.

### **Content of the Research Portfolio**

The U.S. government funds a broad range of research in Gulf War veterans' illnesses. Figure 2-1 illustrates the distribution (by numbers of studies) of the federal research commitment specifically dedicated to Gulf War veterans' health. These studies are not equivalent in terms of cost, number of participants, or likely contribution to understanding Gulf War veterans' health. Appendix F categorizes the research portfolio by type of study and lists the health issue(s) under investigation, research institution, funding agency, anticipated completion date, and publications to date.<sup>295</sup>

**Epidemiologic studies.** As of Fall 1996, the federal government has funded 23 epidemiologic studies (22 percent of the total number of studies). These projects are intended to evaluate the occurrence of disease in Gulf War veterans and the factors that influence their occurrence, severity, and outcome. Individual studies examine different groups of veterans and different diseases and health outcomes. For example, subgroups include women veterans, servicemen and women from countries other than the United States, veterans who have enrolled in the VA Registry, veterans who now live in specific states, veterans who have been hospitalized, and specific veteran groups such as the Seabees. Health outcomes under investigation include cancer rates; rates of infertility, birth defects, and miscarriages; causes of death since return from the Gulf War; general well-being; current health status; and operational case definitions that have been empirically developed for specific subgroups of veterans.

Most of the major, federally funded epidemiologic studies were reviewed in the Committee's *Interim Report*. Upon completion, this epidemiologic research aims to answer some fundamental questions about the health of Gulf War veterans: Are Gulf War veterans as a population exhibiting specific symptoms, diseases, and death at a greater rate than seen in veterans who did not serve in the Gulf War? If so, what are the specific diseases or causes of death that are increased? Results from this epidemiologic research will be crucial for identifying future research needs, as well as which risk factors should receive additional research attention.

**Gulf War risk factors and health outcomes.** Health outcomes for Gulf War veterans under investigation in Fall 1996 included reproductive health; diarrhea and gastrointestinal disorders; irritable bowel-like disorders; immunological function; respiratory function; fibromyalgia; musculoskeletal symptoms; sensitivity to chemicals; fatigue, stress, mental health, and neurophysiologic and neuropsychologic status (including PTSD and Chronic Fatigue Syndrome (CFS)). Many of the projects on specific health outcomes also are based on epidemiologic approaches.

Currently, stress is the risk factor funded for the greatest fraction of total studies-32 studies (30 percent). Other federally funded research investigating possible health effects of specific Gulf War risk factors-often involving animal models-include projects assessing mustard agent; organophosphorus (OP)



factors-often involving animal models-include projects assessing mustard agent; organophosphorus (OP) nerve agents; DU; infectious disease, especially leishmaniasis; oil-well fire smoke; leaded fuels; and PB in combination with insecticides and other agents (figure 2-1).

As summarized in figure 2-1 and appendix F, the government's research portfolio on possible health consequences related to Gulf War service has directed significant effort toward addressing uncertainties specific to Gulf War veterans. Other portions of the research portfolio, however, can only be justified as anticipating health issues in future conflicts-i.e., the general health consequences of military service.

**Low-level effects of chemical warfare agent exposure.** Newly released information has affected the relative importance of certain risk factors. Prior to June 1996, DOD ignored calls from its own DSB<sup>279</sup> and others for research on the possible long-term health consequences of low-level exposure to CW agents. DOD's intransigence in refusing to fund such research until Summer 1996 has done veterans and the public a disservice.

The recent revelations about possible exposure of some U.S. service personnel to low levels of CW agents during the destruction of Iraqi chemical munitions at Khamisiyah have elevated this research issue, however, and altered DOD's posture toward funding such projects. As of November 1996, the RWG was developing the government's approach to fund research in this area. The RWG will need to consult with experts in and out of government to ensure that difficulties (e.g., institutional barriers, inadequate access to expertise, and lack of a clear management strategy) do not impede progress in this important research area.

DOD has committed \$5 million from fiscal year 1996 funds for collaborative DOD/VA research-as identified by the RWG-on possible low-level effects from CW agents. Projects initially slated to receive funds (\$2.5 million) include three previously unfunded proposals based on animal model experiments. Current plans are to identify and fund additional clinical and epidemiologic studies on this topic with the remaining \$2.5 million. DOD's recently announced plans to increase funding for all research on Gulf War veterans' illnesses could result in additional funds for study of low-level exposures to CW agents. In early December 1996, DOD issued a solicitation for proposals for such research.

### Findings Regarding Research

Based on the government's response to the recommendations in the Committee's *Interim Report*, a review of the federally funded research portfolio for Gulf War veterans' health, and a parallel, but independent, review of potential health risk factors that could be associated with service in the Gulf War (see chapter 4), we make the following findings:

- DOD and VA have not taken serious steps to encourage their principal investigators to convene and use public advisory committees for its Gulf War veterans' epidemiologic health research.
- DOD's Persian Gulf Registry of Unit Locations lacks the precision and detail necessary to be an effective tool for the investigation of exposure incidents. The effort has been no more successful than the effort to compile similar information following the Vietnam War to examine possible exposures to Agent Orange.
- Overall, the government's current research portfolio on Gulf War veterans' illnesses is appropriately weighted toward epi
- demiologic studies and studies on stress-related disorders that are more likely to improve our understanding of Gulf War veterans' illnesses. For the most part, the government's prioritization process has worked.
- Research on Gulf War veterans' illnesses is treated, appropriately, as a subset of the government's broader research portfolio on the health consequences of military service. Any new research funds should be directed toward the principal uncertainties, which are: long-term health effects from stress; long-term health effects from low-level exposure to chemical weapons; long-term health effects from exposure to known carcinogenic and mutagenic compounds, such as mustard agent; and long-term health effects of interactions between pyridostigmine bromide and other agents.
- Stress is not well understood in terms of diagnoses, physiological sequelae, and effective prevention and treatment strategies; yet it is likely to be an important contributing factor to illnesses currently reported by Gulf War veterans. Additional attention to basic and applied



illnesses currently reported by Gulf War veterans. Additional attention to basic and applied research on stress-related disorders across the entire federally funded biomedical research portfolio would benefit DOD's and VA's capabilities to manage combat stress and its effects.

- The efforts of the Coordinating Board's Research Working Group would benefit from the active participation of additional representatives from other federal agencies with relevant expertise, such as the National Institutes of Health and the Agency for Toxic Substances and Disease Registry.
- VA's November 1996 establishment of a new Environmental Hazards Center focused on reproductive health and developmental outcomes from environmental exposures is an important step forward in developing policies for the treatment of veterans and addressing their concerns.

The Committee's recommendations for governmental actions based on these findings appear on page 53 of the printed version of the *Final Report*.

## CHEMICAL AND BIOLOGICAL WEAPONS

At the time the Committee issued its *Interim Report*, we were still in the initial stages of reviewing information gathered by the United Nations Special Commission on Iraq (UNSCOM) since the end of the Gulf War about Iraq's advanced CBW capabilities. UNSCOM's work, which continues today, has played a critical role in discovering the extent of possible exposures of U.S. troops to CBW agents during the Gulf War.<sup>262</sup>

In our *Interim Report*, we found the decisions of DOD and the Central Intelligence Agency (CIA) to reopen their investigations of chemical and biological weapons in the Gulf War to be constructive steps and urged DOD and CIA to draw fully on their resources to answer some of the

war's most controversial questions. We stated our intention to monitor their progress carefully. Additionally, we found that improved technology to detect the presence of CBW agents would improve the health surveillance of troops involved in future conflicts. The Committee made the following recommendations related to chemical and biological weapons in the *Interim Report*:

- CIA and DOD should coordinate their analyses to ensure a comprehensive review of the complete record of the Gulf War. Each agency should make full and prompt disclosure of all findings.
- DOD should devote more attention to monitoring low-level (subacute) exposures to chemical warfare agents. One possible basis for such a system is the automated air-sampling system developed by the U.S. Army Edgewood Research, Development and Engineering Center for the United National Special Commission on Iraq, which is using it to monitor emissions from Iraqi chemical plants. Another approach might be to modify the detection system the U.S. Army uses to monitor for leaks at chemical weapons storage depots.
- DOD should continue to invest in the development of a biological point detector/alarm system that can detect and identify biological warfare agent aerosols rapidly enough to enable troops to take protective measures before being exposed.

This section of the *Final Report* includes the Committee's assessment of the government's response to our *Interim Report* recommendations and includes additional findings and recommendations on issues related to chemical and biological weapons.

## DOD AND CIA RESPONSES

As described more fully later in this chapter, CIA has systematically reviewed classified and open source information related to CBW agent exposures during the Gulf War. In contrast, DOD has failed to take advantage of its unique access to both classified and routine military operations and intelligence records. DOD has not accepted or implemented the Committee's recommendation to develop and implement low-level CW agent monitoring. DOD has not made substantial progress in fielding a real-time biological agent detector.<sup>331</sup>

The Committee notes that in a series of studies since the end of the Gulf War in 1991, the U.S. General Accounting Office (GAO) has identified several inadequacies in the U.S. military's preparedness for chemical or biological attacks, and GAO has briefed the Committee on these matters.<sup>66.307.308</sup> While

chemical or biological attacks, and GAO has briefed the Committee on these matters.<sup>66,307,308</sup> While DOD has agreed with virtually all of GAO's findings and recommendations, the Committee is concerned that the equipment, training, and medical shortcomings still persist and could result in needless casualties and a degradation of U.S. war fighting capability.

### Issues New to This Report

To complete its evaluation of information related to reports of possible detections of CW or BW agents during the Gulf War, the Committee focused on two questions:

- What conclusions can be drawn about exposures given the evidence collected to date?
- How vigorously has the government pursued the search for evidence?

The Committee purposely separated these issues from its assessment of the possible health effects of CBW agents, which is discussed in chapter 4.

### Evidence of Exposure

Drawing from a number of sources, including interviews with veterans, operational and intelligence logs, UNSCOM reports, and testimony, briefings, and reports from CIA and DOD, the Committee reviewed evidence of exposure to CBW agents. Ultimately, we identified three possible exposure scenarios for analysis: intentional use of CBW agents by the Iraqis; theater-wide contamination from air war bombings in Iraq; and site-specific exposures related to bombings or demolition activities.<sup>279,313</sup> The Committee has drawn its conclusions with full knowledge that ongoing investigations could disclose additional evidence and does not intend for our work to foreclose full consideration of new information.

**Exposure to biological warfare agents.** The Committee's review of U.S. Army hospital admissions records identified only one admission for anthrax (a disease indigenous to the Gulf region) and none for botulinum poisoning. Stateside laboratory analyses also have not indicated BW agents were present in the KTO. Reports of dead animals that could have succumbed to biological warfare agents have been investigated by DOD, and the evidence does not implicate biological warfare. Finally, Iraqi officials have denied any use of biological weapons during Operations Desert Shield/Desert Storm. Thus, the best evidence available to the Committee indicates U.S. personnel were not exposed to biological warfare agents during the Gulf War.<sup>35,51,52,119,148,274</sup>

This conclusion is based on imperfect information. For instance, UNSCOM cannot verify the quantities and weaponization status of Iraqi BW agents because Iraq claims it unilaterally destroyed all of its biological weapons.<sup>51,162</sup> Additionally, the United States did not deploy a real-time BW agent detection system to the Gulf.

**Intentional Iraqi use of chemical warfare agents.** Iraq successfully used chemical weapons in its war with Iran, with massive casualties not seen in the Gulf War. A DOD review of U.S. Army hospital admissions records identified no admissions for CW agent exposures. The U.S. Army officer responsible for CBW agent medical surveillance during the war has testified to the Committee that only one, accidental casualty was treated (discussed below). Additionally, UNSCOM reported to us that Iraqi officials have denied to them any use of chemical weapons during the war. Lastly, veterans groups testifying before this Committee concede there were no widespread chemical attacks. Based on information compiled to date, there is no persuasive evidence of intentional Iraqi use of CW agents during the war.<sup>35,51,52,119,148,249,261,274</sup>

Again, the best available information is less than ideal. Iraqi representations cannot always be taken at face value. And, some veterans have not received satisfactory explanations for wartime incidents they believe involved chemical weapons.<sup>74,144,249,323</sup>

**Theaterwide chemical warfare agent contamination from air war bombings of Iraq.** During the Gulf War, Coalition forces conducted air attacks on suspected Iraqi CW agent manufacturing and storage facilities. Some veterans and independent researchers have suggested that fallout from Coalition

storage facilities. Some veterans and independent researchers have suggested that fallout from Coalition bombing of these sites led to large-scale nerve agent contamination in the KTO.<sup>261,313</sup> The Committee looked at evidence of the effects of Coalition airstrikes on Iraqi chemical munitions storage sites to examine this hypothesis.

In late January and February 1991, Coalition forces conducted aerial bombings that damaged chemical munitions stored at two sites in central Iraq: Muhammadiyat and Al Muthanna. Subsequent UNSCOM investigations indicate these are the only sites (among 11 known storage sites) where Coalition airstrikes actually damaged or destroyed chemical agents. At Muhammadiyat, munitions containing 2.9 metric tons of sarin/cyclosarin and 15.2 metric tons of mustard were damaged during the air war. At Al Muthanna, munitions containing 16.8 metric tons of sarin/cyclosarin were damaged during the air war.<sup>35,51,148,274</sup>

To assess possible hazards to U.S. forces from CW agent releases at Muhammadiyat and Al Muthanna, atmospheric modeling was conducted for the CIA for all possible bombing dates at each site. This modeling indicates that on the bombing date when southerly winds were most pronounced, Muhammadiyat releases, at worst, would have resulted in downwind contamination for up to 300 kilometers (km) at general population exposure levels established by DOD. This modeling also indicates that on the bombing date when southerly winds were most pronounced, Al Muthanna releases, at worst, would have resulted in downwind contamination for up to 160 km at general population exposure limits. (The general population exposure is a threshold at which one would not expect to see characteristic signs and symptoms of CW agent exposure.) During the air war, the nearest U.S. personnel were in Rafha, Saudi Arabia-more than 400 km from Muhammadiyat and Al Muthanna. Figure 2-2 depicts the locations of the damaged munitions and the closest U.S. forces during the Gulf War.<sup>35,51,148,158,162,274</sup>

The Committee frequently heard the suggestion that air strikes on An Nasiriyah caused CW agent contamination as far away as King Khalid Military City, Saudi Arabia.<sup>261,313</sup> Onsite inspections by UNSCOM, however, found no evidence that chemical munitions were damaged at An Nasiriyah. Iraqi officials also have stated to UNSCOM that chemical munitions stored there were moved to Khamisiyah when An Nasiriyah was first subjected to airstrikes, although the Iraqis have not cooperated fully with the UNSCOM investigations.<sup>51</sup> The best evidence available, indicates theaterwide contamination with CW agent fallout from the air war is highly unlikely.<sup>35,158,274,281,330</sup>

**Site-specific chemical agent exposures.** During the period U.S. forces were deployed in the KTO, incidents occurred at specific sites that resulted in confirmed exposure, detection, or release of CW agents. In testimony and submissions to this Committee, DOD has taken the position that chemical agent exposures can be confirmed only through physical symptoms.<sup>119,148</sup> The Committee believes this approach is analytically flawed and that medical symptoms should not drive a determination of presumed exposure/nonexposure.

Confirmed mustard agent exposure. On March 1, 1991, a soldier exploring a captured bunker in southern Iraq suffered a burn that DOD now confirms was caused by mustard agent. Two mass spectrometer tests by Fox vehicles detected mustard agent on the flak jacket worn by U.S. Army Sergeant Fisher, who was diagnosed as suffering from a chemical agent burn. DOD does not view negative results from subsequent laboratory tests on the jacket and urinalysis as inconsistent with the signs of low-level exposure exhibited by the soldier. DOD now acknowledges the site-specific exposure of mustard agent of this individual.<sup>13,52,148,279,323</sup>

Confirmed nerve and mustard agent detections. On January 19, 1991, shortly after the beginning of the air war, Czech units reported detecting nerve agent at two locations northeast of Hafir al Batin, Saudi Arabia. On January 24, 1991, Czech units also reported detecting mustard agent at a site 10 km north of King Khalid Military City, Saudi Arabia. DOD has verified the reliability of the Czech equipment and regards these detections as valid, but cannot identify a source of the CW agents for either detection.<sup>13,148,281,330</sup> The Czech detections represent un rebutted evidence of the presence of CW agents at these sites, and low-level exposure-at the detection sites-must be presumed.

As noted earlier in this section, worst-case modeling of known CW agent releases at Muhammadiyat and Al Muthanna indicates potential contamination would not have reached the Czech forces. Although there is no evidence of CW agent release from bombing of An Nasiriyah, worst-case modeling conducted for CIA also eliminates this hypothetical release as the source of the Czech detections-i.e., evidence indicates An Nasiriyah, Muhammadiyat, and Al Muthanna were not the CW agent sources for the positive Czech findings. This inability to identify a source for the Czech-detected CW agents precludes modeling the range of exposures around the detection sites. CW agents also were not detected by U.S. troops sent to confirm the Czech findings. Currently, it is not possible to identify low-level exposure of any U.S. troops associated with these two Czech detections.<sup>13,35,51,148,158,274,281,330</sup>

Confirmed nerve agent releases at Khamisiyah. In the ceasefire period after the ground war concluded, U.S. personnel used explosives to destroy captured munitions and other materiel throughout occupied areas of southern Iraq so that enemy forces could not use them to rearm. One such site was a major storage depot at Khamisiyah, where more than 100 large bunkers containing artillery rounds, rockets, and other munitions were destroyed in March 1991.<sup>119,147,148</sup>

DOD has testified to the Committee that on March 4, 1991, U.S. personnel destroyed munitions containing 8.5 metric tons of sarin/cyclosarin housed in Bunker 73 at Khamisiyah. On March 10, 1991, U.S. personnel destroyed an as yet unknown number of sarin/cyclosarin rockets at a pit area at Khamisiyah.<sup>119,148</sup>

Atmospheric modeling conducted for CIA indicates CW agent release from Bunker 73 would result in downwind contamination for up to 25 km at general population exposure limits<sup>35,158</sup> (figure 2-3). U.S. personnel with the 37th Engineering Battalion, 307th Engineering Battalion, 60th Explosive Ordnance Detachment, 146th Explosive Ordnance Detachment, 450th Civil Affairs Battalion, and other components of the 82nd Airborne Division were within 25 km of Khamisiyah.<sup>58,119,147,148</sup> The footprint of the March 10, 1991, release and other possible releases at the Khamisiyah pit area are still under investigation.<sup>230,331</sup>

The evidence of CW agent release at Khamisiyah is overwhelming. The Committee concludes exposure should be presumed for nearby troops, although the exact levels are unknown. The presumption of exposure does not include a presumption of long-term health effects (see chapter 4). As of this writing, DOD has initiated an effort to notify all troops within a 50 km radius around Khamisiyah between March 4 to March 13, 1991, that they could have been exposed to low levels of CW agents.<sup>331</sup> These actions appear prudent in light of what is known about the destruction of Bunker 73, but additional steps could be necessary once the full extent of Khamisiyah demolition activities is known.

## Search for Evidence

The U.S. government has relied on CIA and DOD internal investigations to report evidence of exposure of U.S. troops to CBW agents. CIA was assigned two responsibilities: reviewing intelligence information relevant to possible CBW agent exposures and performing downwind hazard modeling for possible CW agent releases.<sup>35</sup> DOD's investigatory efforts have been led by PGIT, which reports to the Assistant Secretary of Defense (Health Affairs). PGIT's scope spans the broad range of issues related to Gulf War veterans' illnesses. Additionally, a DOD Senior Level Oversight Panel for Gulf War veterans' illnesses coordinates the declassification and release of documents related to CBW agents and other potential risk factors.<sup>104,119,325</sup>

**CIA's investigation.** In March 1995, CIA began a *de novo* review of intelligence related to CBW agents and the Gulf War; its work in atmospheric modeling began in early 1996. To date, CIA has aggressively pursued information related to possible CBW agent exposures from classified and open sources. With respect to downwind hazard modeling, CIA has been responsive to the Committee's concerns about potential low-level contamination and has modified modeling assumptions and parameters to reflect these concerns. In August 1996, CIA reported on the bulk of its analysis but the agency has yet to complete atmospheric modeling for the March 10, 1991, destruction at the Khamisiyah pit area.<sup>35,158,230,274</sup>

area.35,158,230,274

**DOD's investigations.** Since 1991, DOD's public position has been there was no use or presence of chemical weapons in the KTO, and no U.S. troops were exposed to CBW agents during the Gulf War. DOD maintained this position throughout a series of congressional investigations in late 1993 and early 1994. In June 1994, a DSB Task Force concluded there was "no evidence that either chemical or biological warfare was deployed at any level against us, or that there were any exposures of U.S. service members to chemical or biological warfare agents in Kuwait or Saudi Arabia." The DSB Task Force was silent on the issue of exposures to service members in Iraq, but its conclusion was interpreted by DOD as inclusive.119,279,313

**Persian Gulf Veterans' Illnesses Investigation Team.** PGIT's 12-member staff includes intelligence officers, members of the Chemical Corps, pilots, chemists, physicians, and one trained investigator. Reflecting its staffing, PGIT has devoted substantial resources to literature reviews and scientific studies, rather than collecting first-hand evidence of possible CBW agent exposure incidents from eye witnesses, battlefield intelligence, unit logs, diaries, and other original documents. By doing so, PGIT has failed to take advantage of its unique access to classified and routine military records to fully investigate and help answer the public's questions about possible CBW agent exposures.119,148,163,169 PGIT's investigation of the Khamisiyah incidents represents the sole exception to this situation.

Khamisiyah first appeared on PGIT's list of incidents under investigation in October 1995 material supplied to the Committee. Yet, PGIT conducted no interviews with possible eyewitnesses until June 1996. PGIT had knowledge of documents, including UNSCOM reports and declassified intelligence reports posted to GulfLINK, that suggested a sufficient basis to initiate investigatory interviews long before UNSCOM confirmed in May 1996 its initial reports about the presence of CW agents. PGIT's recent eyewitness interviews and its efforts to ascertain troop locations have been valuable, however, in trying to find answers about the Khamisiyah incidents.119,325

More importantly, other possible CW agent incidents also merit a thorough review and full investigation. Chief among these are positive readings recorded by two types of detectors fielded to verify chemical agent alarms: Fox reconnaissance vehicles equipped with mobile mass spectrometers and M256 kits, which employ enzymatic tests for nerve agents and chemical tests for blister agents. Fox reconnaissance vehicles detected blister and nerve agents at various sites in Kuwait and Saudi Arabia, and M256 kits also detected the presence of CW agents during the ground war.74,144,249,323 Rather than thoroughly investigate these site-specific incidents, PGIT plans to include them in a theater-wide time/distance analysis.119,148

In response to our questions in May 1996 about potential low-level CW agent exposures, PGIT first reported it had no formal, objective standard(s) for assessing whether CBW agent detections should be confirmed or not confirmed. Two months later in July 1996, PGIT reported to the Committee that it had adopted military CBW agent detection standards to confirm the occurrence of an exposure. This standard requires both agent detections and physical symptoms of poisoning.119,148

The Committee faults PGIT on two counts in this regard: first, for its delay in adopting standards until, as PGIT admitted, it was pressed by the Committee more than a year after it began its work; and second, for confusing the matter of potential CW agent exposure with the separate issue of possible health effects of CW exposure. Adherence to this standard-even when assessing possible low-level exposures that do not cause immediate physical symptoms-has severely undermined public confidence in DOD's work on CBW agent issues. PGIT's analyses related to CBW incidents have lacked vigor, fallen short on investigative grounds, and stretched credibility.

In November 1996, DOD introduced some organizational changes related to its work on Gulf War veterans' illnesses. As part of this reorganization, DOD announced plans to revamp its investigatory and research programs related to low-level CW agent exposure.331 These efforts, combined with publicly visible, independent, high-quality oversight, could begin to restore public confidence in the government's investigations of possible incidents of CW agent exposure.

Enhancing public access to information. DOD's slow and erratic efforts to release information to the public have further served to erode the public's trust. As of December 1996, 5 of 54 PGIT investigations have generated reports posted on DOD's GulfLINK Internet site. DOD typically has posted testimony before this Committee on GulfLINK, but the department has not posted status reports on its investigations that it prepared for the Committee in August 1996.<sup>119,325</sup> Public access to more information could only enhance DOD's reputation among parties interested in these issues.

DOD's pledge to post copies of relevant declassified documents to GulfLINK also has proved problematic. In November 1995, DOD officials instructed that before declassifiers posted sensitive documents, they should forward the material to PGIT "to allow the investigation Team time to begin preparation of responses on particular 'bombshell' reports".<sup>324</sup> Separately in February 1996, nearly 400 declassified documents were removed from GulfLINK due to security concerns of CIA.<sup>230</sup> DOD reported to the Committee that the documents were not reclassified, but the documents were not restored to GulfLINK until November 1996.<sup>331</sup> These actions clearly have created the impression that the government, particularly DOD, has failed to live up to repeated assertions and commitments to openness in its work related to CBW agent investigations and the Gulf War.<sup>119,144,163,249,325</sup> Nationwide, there has been an increasingly strongly held view that DOD is still withholding relevant information from concerned veterans and the public.

### **Findings Regarding Chemical and Biological Weapons**

Based on interviews with veterans, review of operational and intelligence logs, UNSCOM reports, testimony, briefings, and reports from CIA and DOD, the Committee makes the following findings:

- In the face of credible evidence of the presence or release of chemical warfare agents, low-level exposure of U.S. personnel at the affected site must be presumed while efforts to develop more precise measures of exposure continue.
- The evidence of chemical warfare agent release at Khamisiyah is overwhelming, and low-level exposure to troops within a 50 kilometer radius should be presumed while efforts to develop more precise measures of exposure and more detailed knowledge of the demolition activities continue.
- Other site-specific exposures of U.S. troops to low levels of chemical warfare agents cannot be ruled out. A theater-wide time/distance analysis is insufficient to address positive detections by Fox reconnaissance vehicles and M256 kits.
- DOD has conducted a superficial investigation of possible chemical warfare agent exposures that is unlikely to provide credible answers to veterans' and the public's questions.

The Committee's recommendations for governmental actions based on these findings appear on page 54 of the printed version of the *Final Report*.

### **COORDINATION**

The President established the Coordinating Board on January 21, 1994, to provide direction and coordination on health issues related to the Gulf War within the executive branch of the federal government. Earlier in this chapter, we reviewed the role of the Coordinating Board's RWG in managing the Gulf War veterans' health research of DOD, VA, and DHHS. Here we analyze the RWG's other tasks and also evaluate the Coordinating Board's two other working groups: the Clinical Working Group (CWG) and the Disabilities and Benefits Working Group (DBWG). Finally, we have assessed the government's ability to respond to the broad range of issues—from the need for medical care and outreach services, to the need for research on general and specific health concerns—likely to arise after future conflicts.

#### **Coordinating Efforts Specific to Gulf War Health Issues**

The Secretaries of DOD, DHHS, and VA head the Coordinating Board. The Coordinating Board's three primary missions are:

- to provide all veterans the complete range of health care services necessary for medical problems that might be related to deployment in Operations Desert Shield/Desert Storm;
- to develop a research program that will result in the most accurate and complete understanding of the types of health problems being experienced by Gulf War veterans and the factors that have contributed to these problems; and
- to develop clear and consistent guidelines for the evaluation and compensation of disabilities related to Gulf War service.<sup>2</sup>

The Coordinating Board established a working group to oversee each primary mission. As a preliminary matter, the Committee found the assistance of the Coordinating Board and participants in the working groups invaluable. In addition, we recognize the difficulty of integrating the activities of large departments with disparate missions to achieve a whole greater than the sum of its parts. The Committee commends the dedication of the staff involved in these efforts.

**Clinical Working Group.** The CWG oversees delivery of care to Gulf War veterans. The Committee found that, overall, high-quality health care is provided. We recommend, however, some improvements in CME and a regular review of staffing requirements to ensure adequate access to follow-up care.

VA introduced its clinical Registry program in 1992 and refined the physical examination and associated questionnaires over the next two years; DOD and civilian medical professionals were consulted as the program matured. DOD adopted VA's standardized evaluation protocol for its CCEP in 1994, and both departments continue to use the same protocol. This Committee and others have judged the protocol to be an excellent tool for diagnosing illness.

The CWG serves as a useful counterpart to the RWG by ensuring coordination of the research plan with interesting hypotheses that might emerge from the clinical programs. The CWG also has an important role to play in disseminating information about the clinical programs and in communicating the results of the research program to health professionals in DOD and VA medical facilities.

**Research Working Group.** In its *Interim Report*, the Committee identified the need for a more aggressive stance by the RWG in emphasizing the importance of utilizing peer review committees when planning and conducting research and in coordinating the design of epidemiologic surveys. Overall, the RWG has been responsive to our recommendations. A peer review process was used to identify scientifically meritorious proposals that were funded in 1996 (in response to DOD's BAA issued in 1995). Ongoing government-sponsored epidemiologic surveys of Gulf War populations include a core set of similar questions regarding symptoms and exposures that should enable appropriate comparisons among study groups. Future investigators will be encouraged to incorporate the RWG-developed set of core questions in their work.

The RWG has set priorities for new research on Gulf War veterans' illnesses. And the group has overseen the publication of research compendiums and efforts to cooperate with U.S. allies in the Gulf War in future health research.

**Disabilities and Benefits Working Group.** The DBWG initially addressed itself to a broad range of issues, including case definitions for disabilities with vague symptoms, care for family members of Gulf War veterans, and DOD's outreach program on Gulf War veterans' health issues. Late in 1994, this working group took as its primary responsibility coordination of the executive branch response to Public Law 103-446, which authorized compensation to Gulf War veterans for disabilities resulting from undiagnosed illnesses. VA issued an implementing regulation (38 CFR 3.317) in February 1995. The DBWG continued to meet through June 1995 to discuss the impact of the new legislation and regulation. The only meeting in 1996 to date occurred for the purpose of briefing this Committee's staff on pay and benefits for individuals separated from service; DOD's disabilities evaluation process; military retirement and separation for disability; comparison of the departments' use of VA's schedule for rating disabilities; and VA's compensation and evaluation procedures.

VA currently is reviewing how effectively it has managed its program of compensation for undiagnosed



illnesses. A randomized case review by VA's Compensation and Pension Service (prompted, in part, by a GAO report<sup>310</sup>) disclosed frequent instances of miscategorization in the tracking system and failures to develop evidence-particularly lay observations-that might affect the outcome of a claim. As a result of this review, VA reported to the Committee that as of July 1996, it had undertaken a complete second review of all 11,000 cases in the tracking system to ensure full evidentiary development, correct adjudication, and accurate coding in the tracking system. VA also issued more detailed instructions emphasizing these points. VA expected the review of 11,000 cases to take six months and reported its intent to work closely with DOD.

### **Anticipating Post-conflict Health Concerns**

Several concerns identified during the Committee's examination of Gulf War veterans' illnesses-issues related to research, outreach, and clinical programs-have surfaced after previous conflicts (e.g., effective epidemiology in the absence of baseline exposure and health information; risk communication with veterans concerned about environmental hazards; and uncertainties about the health consequences of environmental exposures). Responsibility for resolving concerns that invariably arise in the aftermath of military conflicts lies within the domain of several departments, yet appears to be a principal focus of no agency. Following a military operation, effort is exerted in a reactive, rather than proactive, manner.

The departments principally involved in Gulf War veterans' illnesses-DOD, VA, and DHHS-have had historical responsibilities for other, similar post-conflict issues, but a number of other agencies also have important expertise and interest. These entities include EPA, CIA, the Department of Energy, the National Science Foundation, the Department of Commerce, and the Department of State. Along with DOD, VA, and DHHS, all are members of the National Science and Technology Council (NSTC), an interagency coordinating body established to ensure cross-agency attention to matters of critical national importance.

The lessons learned from the Committee's analyses of Gulf War veterans' health concerns point toward post-conflict health needs of veterans as precisely such a matter. A Presidential Review Directive to the NSTC could be used to ensure the government formulates a comprehensive strategy to deal with key concerns that arise following significant military operations, including:

- health (e.g., stress prevention, treatment, research; medical surveillance adequacy, coordination; interventions for families);
- outreach and risk communication;
- recordkeeping (e.g., accountability, timeliness, cross-agency coordination, application of new technologies);
- research (e.g., adequacy, quality, coordination, dissemination of results);
- biological and chemical weapons preparedness and research;
- application of emerging technologies (e.g., telemedicine, technology transfer); and
- international cooperation and coordination, especially on research and technology matters.

Any plan developed by NSTC should be reviewed by appropriate nongovernmental experts to ensure that these recurring concerns receive attention at the highest national levels.

### **Finding Regarding Coordination**

Based on its analysis of the government's efforts to coordinate the response to Gulf War veterans' illnesses, the Committee makes the following finding:

- Many issues related to post-conflict health concerns of Gulf War veterans are common to the aftermath of other military engagements. Governmental responsibility to address such concerns spans the missions of several federal departments and agencies, but is a priority for no agency. Resolving these issues in a timely and effective manner requires interagency coordination at the highest levels of government.

The Committee's recommendation for governmental action based on this finding appears on page 55 of



the printed version of the *Final Report*.

## SUMMARY

The President asked that we review the full range of government activities relating to Gulf War veterans' illnesses. In the *Interim Report*, we organized our analyses of the government's efforts into four broad areas: outreach, medical and clinical issues, research, and chemical and biological weapons. In this document, we make additional findings and recommendations to complete our initial assessments in these areas; we also address coordination for the first time.

With the exception of DOD's investigations in matters related to incidents involving chemical weapons and possible exposure to U.S. troops, we believe the government has acted in good faith and drawn on a somewhat checkered experience with Agent Orange to significantly improve how it has addressed Gulf War veterans' health issues. Hence, we note that although our recommendations are many, they are offered to improve the government's generally commendable response. Their number and scope should not be viewed as a wholesale condemnation or cause for a complete overhaul of the government's approach to addressing the health concerns of Gulf War veterans.

## RECOMMENDATIONS

The Committee's evaluation of the government's response to concerns about Gulf War veterans' illnesses led us to findings in outreach, medical and clinical issues, research, chemical and biological weapons, and coordination. Based on our analyses and these findings, the Committee makes the following recommendations:

### Outreach

- DOD and VA should follow the model of field-based outreach demonstrated in the Vet Centers and the Persian Gulf Family Support Program when developing health education and risk communication campaigns for active duty service members, Reserve and National Guard personnel, and other veterans. General, less specific outreach methods-e.g., hotlines and public service announcements-should be viewed as important supplements, but not as replacements.
- VA should direct its Transition Assistance Program workshop benefits counselors to specifically mention DOD and VA programs related to Gulf War veterans' illnesses.
- VA should ensure that its initiatives under the Women Veterans Health Programs specifically provide information about Gulf War-related programs.
- VA should ensure that its outreach to Latino populations specifically provides information about Gulf War-related programs. As the Committee stated in its *Interim Report*, DOD and VA should develop and utilize more refined performance measures to determine how well outreach services are reaching concerned parties. DOD and VA officials (specifically those in the American Forces Information Service and its broadcasting arm, the Armed Forces Radio and Television Service) using media products for outreach initiatives should be aware of the difficulty in enumerating the actual readership and viewership figures and be concerned about how effectively their message saturates the targeted population.
- DOD should reissue its *Internal Information Plan* on Gulf War-related illnesses. It should make a special effort to note the revision provides the toll-free number and that individuals are encouraged to register for its Comprehensive Clinical Evaluation Program. It also should take this opportunity to provide updated information.
- In an attempt to increase veterans' and the public's awareness and understanding of the full range of the government's commitment to addressing the nature of Gulf War veterans' illnesses, DOD and VA should reevaluate the goals and objectives of their risk communication efforts. DOD and VA should develop effective methods that provide the affected community with comprehensive information concerning possible exposures to environmental hazards, potential health effects from risk factors, and explanations of ongoing and completed clinical and epidemiologic studies.
- DOD and VA should immediately develop and implement a comprehensive risk communication plan. This effort should move forward in close cooperation with agencies that have a high degree of public trust and experience with risk communication, such as the Agency for Toxic Substances

- and Disease Registry and the National Institute for Occupational Safety and Health.
- Because health risk information and education applies to service members who remain on active duty, members of the Reserves and National Guard, and veterans no longer in military service, DOD and VA should closely coordinate the federal government's risk communication effort for Gulf War veterans and other members of the affected community. Departmental commitments to any plan should be viewed as continuous and long-term; a sustained effort is particularly critical in light of veterans' and public skepticism arising from the recent revelations related to chemical weapons.
- In its coordinated risk communication plan, DOD and VA should engage veterans service organizations as intermediaries-and include personnel in leadership positions, such as senior enlisted personnel (for active duty military) and state veterans' service officials-in the effort to establish an efficient information exchange process where veterans receive accurate information and the departments receive valuable feedback on clinical programs, health concerns, and communication efforts.

## Medical and Clinical Issues

- Given that the Food and Drug Administration's (FDA) Interim Final Rule permitting a waiver of informed consent for use of unapproved products in a military exigency is still in effect, DOD should develop enhanced orientation and training procedures to alert service personnel they may be required to take drugs or vaccines not fully approved by FDA if a conflict presents a serious threat of chemical and biological warfare.
- FDA should solicit timely public and expert comment on any rule that permits waiver of informed consent for use of investigational products in military exigencies. Among the areas that specifically should be revisited are: adequacy of disclosure to service personnel; adequacy of recordkeeping; long-term followup of individuals who receive investigational products; review by an institutional review board outside of DOD; and additional procedures to enhance understanding, oversight, and accountability.
- DOD officials at the highest echelons, including the Joint Chiefs of Staff and the Commanders in Chief, should assign a high priority to dealing with the problem of lost or missing medical records. A computerized central database is important. Specialized databases must be compatible with the central database. Attention should be directed toward developing a mechanism for computerizing medical data (including classified information, if and when it is needed) in the field. DOD and VA should adopt standardized recordkeeping to ensure continuity.
- The Persian Gulf Veterans Coordinating Board and other appropriate Departments and Agencies should be charged to develop a protocol to implement the following recommendation, which was made in the Committee's *Interim Report*: Prior to any deployment, DOD should undertake a thorough health evaluation of a large sample of troops to enable better postdeployment medical epidemiology. Medical surveillance should be standardized for a core set of tests across all services, including timely postdeployment followup.
- VA and DOD should, in their educational outreach programs, specifically target staff members not directly involved in the care of Gulf War veterans.
- DOD and VA should include timely updates on the Comprehensive Clinical Evaluation Program or Persian Gulf Health Registry, respectively, in their Continuing Medical Education programs.
- VA and DOD should regularly brief their staffs on the Gulf War research portfolio and on the results of research studies as they become available.
- VA and DOD should regularly review staffing needs, particularly in mental health, and increase recruitment and retention of adequate numbers of medical professionals to satisfy patient needs. Staffing reviews should consider that, despite increased medical surveillance and better preventive measures, future deployments also will generate a significant number of veterans who will need care for illnesses that are difficult to diagnose.
- Since 1986, U.S. service members with certain chronic illnesses, e.g., asthma and diabetes, have been allowed to remain on active duty when regular medical monitoring is necessary. Veterans of the Gulf War with chronic illnesses are no different. Troop commanders should be reminded that adequate time off for follow-up medical appointments is a necessity and a priority.
- The government should conduct a thorough review of its policies concerning reproductive health and seek statutory authority to treat veterans and their families for service-connected problems.

When indicated, genetic counseling should be provided-either via VA treatment facilities or referral-to assist veterans and their families who have reproductive concerns stemming from military service.

- The government should continue and intensify its efforts to develop stress reduction programs for all troops, with special emphasis on deployed troops.
- Since leadership and unit cohesion are so important in managing stress, DOD should specifically involve senior commanders and senior noncommissioned officers in stress management programs.

## Research

- The Research Working Group of the Persian Gulf Veterans Coordinating Board should require that any proposals for new, large-scale Gulf War veterans' epidemiologic health research describe a plan to incorporate a public advisory committee into the study design, dissemination of results, or both. The Research Working Group should consider justifying a waiver of such a committee only under rare circumstances.
- The government should develop more accurate and reliable methods of recording troop locations to facilitate post-conflict health research in the future. DOD should make full use of global positioning technologies.
- The government should plan for further research on possible long-term health effects of low-level exposure to organophosphorus nerve agents such as sarin, soman, or various pesticides, based on studies of groups with well-characterized exposures, including: a) cases of U.S. workers exposed to organophosphorous pesticides; and b) civilians exposed to the chemical warfare agent sarin during the 1994 and 1995 terrorist attacks in Japan. Additional work should include followup and evaluation of an appropriate subset of any U.S. service personnel who are presumed to be exposed during the Gulf War. The government should begin by consulting with appropriate experts, both governmental and nongovernmental, on organophosphorus nerve agent effects. Studies of human populations with well-characterized exposures will be much more revealing than studies based on animal models, which should be given lower priority.
- Since a number of Gulf War risk factors are potential human carcinogens that could result in increased rates of cancer beginning decades after exposure, VA should continue to monitor Gulf War veterans through its ongoing mortality study for increased rates of lung, liver, and other cancers.
- Depleted uranium munitions are likely to be used in future conflicts involving U.S. service personnel. To fully elucidate the health effects of depleted uranium munitions, VA should conduct research that compares the health status of individuals with embedded fragments of DU shrapnel with appropriate control groups.
- The government should continue to collect and archive serum samples from U.S. service personnel when feasible.
- The Research Working Group should more thoroughly consult with other federal agencies with relevant expertise-such as the National Institutes of Health (particularly the National Institute of Environmental Health Sciences) and the Agency for Toxic Substances and Disease Registry-on basic, clinical, and epidemiologic research and on risk communication.

## Chemical and Biological Weapons

- All U.S. service personnel assigned to units near the Khamisiyah demolition activity should be notified and encouraged to enroll in VA's Persian Gulf Health Registry or DOD's Comprehensive Clinical Evaluation Program. In determining the extent of possible chemical warfare agent exposure at Khamisiyah and any other sites that future investigations uncover, the government should use the best theoretical and practical assessment tools available. The Committee recognizes the large number of variables that can affect the outcome of any determination, but identifies the following as essential principles:
  - Where objective, un rebutted evidence suggests the release of chemical warfare agents in the vicinity of U.S. troops, every effort should be made to identify the source of the agent and to model the downwind footprint of the potential distribution of agent at the general population exposure level (or lower threshold, if appropriate);
  - When a downwind footprint is established, a conservative, presumptive-exposure area

should be defined that reflects the uncertainties of the modeling effort. The presumptive-exposure area should, at a minimum, include all sites within a circle that has a radius equal to the length of the downwind footprint; and

- Troops within the presumptive-exposure area should be notified and encouraged to enroll in the CCEP or Registry.
- All reports of positive M256 kits and Fox detections must be thoroughly investigated. Where unit logs record positive detections by either type of equipment, members of that unit should be notified and encouraged to enroll in VA's Persian Gulf Health Registry or DOD's Comprehensive Clinical Evaluation Program.
- To ensure credibility and thoroughness, further investigation of possible chemical or biological warfare agent exposures during the Gulf War should be conducted by a group independent of DOD. Openness in oversight activities-including public access to information and veteran participation-public notice of meetings, opportunity for public comment, and regular reporting are essential. Full public accountability is critical.

## Coordination

- A Presidential Review Directive (PRD) should be issued to instruct the National Science and Technology Council to develop an interagency plan to address health preparedness for and readjustment of veterans and families after future conflicts and peacekeeping missions. The President's Committee of Advisors on Science and Technology and other nongovernmental experts, as appropriate, should be asked to review the plan 12 months after the PRD is issued and again at 18 months to ensure national expertise is brought to bear on these issues.

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\*These services were designed to manage post-traumatic stress disorder, which was the primary readjustment concern.

\*\*Initially, treating post-traumatic stress disorder was the PGFSP's primary focus of clinical services.

\*\*\*At DOD's request, the Institute of Medicine (IOM) evaluated the CCEP, and IOM judged the clinical protocol (also used by VA) excellent for the diagnosis of illnesses. <sup>95</sup>

## **Presidential Advisory Committee on Gulf War Veterans' Illnesses Final Report**

### **Chapter Three**

## **NATURE OF GULF WAR VETERANS' ILLNESS**

Quantitative documentation and analysis of the extent of Gulf War veterans' illnesses remains elusive at this writing. Nevertheless, the clinical programs of VA and DOD, along with preliminary information from several federally funded epidemiologic studies, provide some data that can begin to place Gulf War veterans' illnesses in context. This chapter provides an overview of available data and the Committee's findings and recommendations about the nature of Gulf War veterans' illnesses.

### **DATA FROM CLINICAL PROGRAMS**

As of October 1996, approximately 62,000 individuals had completed physical examinations in VA's Persian Gulf Health Registry, and VA has reviewed results for the first 52,216 veterans.<sup>109</sup> More than 34,000 individuals had requested an examination in DOD's CCEP as of October 1996; information on the first 18,075 military personnel has been reported by DOD.<sup>277</sup>

Information derived from these data sets has clinical utility, and DOD and VA have used the information to address several concerns from a descriptive perspective. The data also have provided guidance in the formulation of certain epidemiologic research approaches. However, results from analyzing the Registry and the CCEP-two self-selected case series-cannot be generalized to the entire population of Gulf War veterans. As described later, scientifically valid, generalizable knowledge is the expected outcome of epidemiologic research currently underway.

#### **Data from DOD's CCEP and VA's Registry**

Gulf War veterans who have participated in the CCEP and Registry represent a broad cross-section of service members who deployed to the Gulf War (table 3-1). To provide a qualitative snapshot of the clinical status of the Gulf War veterans who have participated in the government's clinical evaluation programs, the following sections summarize information-based on material published by DOD and VA-for several key descriptive parameters.<sup>109,277</sup>

**Reported symptoms.** CCEP participants report a broad range of symptoms that span a variety of organ systems (table 3-2). The most common primary symptoms reported are joint pain, fatigue, headache, rash, and memory loss. Ten percent of participants are asymptomatic. The most frequent symptoms in the CCEP also are common in the general adult population in the United States.

The most common symptoms reported by VA Registry participants (table 3-2) nearly match the most common symptoms reported by CCEP participants. Asymptomatic individuals comprise about 12 percent of the Registry population.

**Diagnoses.** Approximately 10 percent of CCEP participants are found to be healthy. The other most common primary diagnostic categories of CCEP participants are psychological conditions; musculoskeletal system diseases (MSDs); and Symptoms, Signs, and Ill-defined Conditions (SSIDC) (table 3-3). Combined, the three categories account for more than 50 percent of primary diagnoses. Other primary diagnoses in the CCEP do not concentrate in any single organ system.

The most common diagnostic categories in VA's Registry are the same as in the CCEP: psychological conditions, MSDs, and SSIDC (table 3-3). As with CCEP participants, the diagnoses do not center in a single organ system beyond these three categories.

**Morbidity/Disability.** To approximate disability due to illness, DOD asks CCEP participants about the number of work days missed due to illness in the 90 days prior to the initial examination. Most

individuals (80 percent) reported no missed days of work due to illness during this time period. Among those reporting one or more lost work days, the median number of lost days was five. This level of lost workdays in the past 90 days exceeds that found for the general U.S. population of civilian employees.<sup>292</sup>

CCEP data on lost workdays, however, cannot be viewed as an estimate of the overall prevalence of disability due to Gulf War service. Many individuals-some of whom could have disabilities-have left active service since the Gulf War and are not eligible for participation in the CCEP. No estimates of the degree of disability have been reported for individuals enrolled in VA's Registry.

**Musculoskeletal system diseases.** MSDs account for 18.3 percent of primary diagnoses in CCEP participants. DOD reports the occurrence of MSDs in the CCEP is about two times higher in male CCEP participants and three times higher in female CCEP participants than the rate of occurrence of MSDs in the general U.S. population aged 20 to 40 years.<sup>277</sup> Whether the rate of MSDs for CCEP participants differs from that for the general military population is unknown, however, due to the paucity of baseline information on the health status of active duty personnel.

Military personnel must maintain certain levels of physical fitness, and many are required to participate in demanding physical training programs, placing considerable stress on joints and muscles. DOD reports that the majority of MSDs diagnosed in CCEP participants are wear-and-tear disorders-e.g., recurrent strains, sprains, and degenerative arthritis due to trauma on a joint-that could be expected in a physically active populace; occupational and recreational overuse injuries also frequently occur as a consequence of the physical activities of military training and operations.<sup>277</sup>

MSDs are the most prevalent diagnostic category among participants in VA's Registry.<sup>109</sup> Additionally, as of September 1995 more than 15,000 Gulf War veterans had been admitted for inpatient treatment to a VA hospital; MSDs account for 21.3 percent of the total diagnoses received by these inpatients.

**Infectious diseases.** Infectious diseases are not a frequent cause of illness among CCEP participants. DOD reports 470 individuals have a primary diagnosis of an infectious disease, and about half of these are infections of the skin due to fungi that are common in the United States. VA's Registry reports similarly low occurrences of infectious diseases among its participants; 7.1 percent have a primary or secondary diagnosis of an infectious disease.<sup>109</sup> For infectious diseases, athlete's foot, a fungal infection of the skin, was one of the most common-occurring in 1.4 percent of the Registry population.

Infectious diseases have affected a variety of organ systems in Gulf War veterans without any observable patterns. Most infectious diseases identified through the clinical programs are minor conditions common among the general population; such conditions do not explain serious, persistent, systemic complaints. To date, few individuals have demonstrated characteristic physical signs and laboratory abnormalities that indicate a chronic infectious process.<sup>65,90,293</sup> Moreover, it is unlikely that Gulf War veterans have infections that have evaded the systematic diagnostic efforts mandated by the standardized protocol.

**Cancer.** Cancer is rare among CCEP enrollees. A primary diagnosis of cancer has been made in 52 individuals (0.3 percent), and the types and frequencies are shown in table 3-4. Lymphomas are the most frequent cancer diagnosed in CCEP participants; lymphomas also are the most common types of cancer among 20- to 40-year olds in the general U.S. population. The second most frequent cancer diagnosis for CCEP participants is skin cancer-again, one of the most common malignancies in the age-matched U.S. general population. Clinical evaluation through the CCEP identified four individuals with testicular cancer, which is a common type of cancer among young men in the U.S. general population.

Cancer also is rare among individuals in VA's Registry. There does not appear to be an unusual incidence of any specific type of cancer in this population. A primary diagnosis of cancer was made in 226 individuals (0.4 percent; table 3-4).<sup>109</sup> The same three types of cancer most common among CCEP participants are the most frequently diagnosed in VA's Registry population: lymphomas, skin cancer, and testicular cancer.

**Data from Great Britain and Canada.** Great Britain implemented a systematic medical evaluation program for Gulf War veterans in late 1993. To date, about 500 individuals have enrolled in the U.K. medical program, and the clinical results for 284 individuals are available.<sup>34</sup> Canada began its medical evaluation program for Gulf War veterans in early 1995, and the clinical information for 49 veterans is available.<sup>227</sup> Both programs are thorough, and the procedures resemble Phase II of the U.S. protocol (see [chapter 2](#)). Because the proportion of eligible Gulf War veterans who have enrolled in these programs is small, physicians involved in both programs view results as preliminary. The Committee draws no conclusions based on the available data from these two countries.

Great Britain. Approximately 45,000 British troops were deployed to the Gulf War. In late 1993, the Ministry of Defense set up a medical evaluation program for these individuals, and in September 1994 a modified version of the U.S. protocol was adopted. About 20 percent of participants remain on active duty.

Information about the first 284 participants (0.6 percent of British troops deployed) was presented publicly in August 1996.<sup>34</sup> [Table 3-5](#) presents the most frequently reported symptoms, which are similar to the symptoms reported by U.S. Gulf War veterans. The most common primary diagnoses in the British participants are also common among U.S. Gulf War veterans ([table 3-6](#)). Fifteen percent of diagnoses for British participants are coded under the SSIDC category. A small percentage of these cases meet the Oxford criteria for CFS, which are slightly less stringent than CDC's criteria.<sup>34</sup> There was a clear relationship between service in the Gulf War and the onset of psychiatric illness in a number of participants in the British evaluation.<sup>214</sup>

Canada. Canada established its medical evaluation program for Gulf War veterans in early 1995 and had enrolled about 60 veterans as of Summer 1996. A compilation of the evaluations for the first 49 participants (about 1.0 percent of the 4,500 Canadian troops deployed to the Gulf) were presented publicly in August 1996.<sup>227</sup>

[Table 3-7](#) presents the ten most frequent symptoms among Canadian participants; these symptoms are nearly identical to the most frequent symptoms reported by U.S. Gulf War veterans. [Table 3-8](#) reports the frequencies of the major diagnostic categories in the 49 Canadian participants. Most of the MSD cases in the Canadian population are mechanical low back pain, osteoarthritis, and degenerative disc disease. Eight percent of the diagnoses are SSIDC.<sup>227</sup>

## DATA FROM EPIDEMIOLOGIC STUDIES

As noted in the Committee's [Interim Report](#), epidemiologic studies are crucial for better understanding of the extent and nature of Gulf War veterans' illnesses. Any large population will include people who are experiencing a variety of different illnesses. While clinical programs provide valuable information, they cannot provide answers to whether and how rates of illnesses or death in the whole Gulf War veteran population differ from those that would be expected in any similar large population. Answers to these questions could focus attention on the most useful and relevant interventions or treatments.

Carefully designed epidemiology studies are time-consuming, and many were not initiated until several years after the Gulf War. Thus, many important studies addressing the general characteristics of Gulf War veterans' illnesses are still underway, and preliminary results are not yet publicly available. These include such studies as VA's National Health Survey and the Health Assessment of Persian Gulf War Veterans from Iowa, as well as several studies at VA's Environmental Hazards Centers. The following sections review data from completed epidemiology studies for which results have been published in the peer-reviewed literature or government reports, or for which preliminary data have been released publicly by the investigators ([table 3-9](#)).

### Mortality Studies

Mortality studies examine deaths among the selected population. Research in this area has focused on

deaths that occurred during and after the Gulf War.

**Mortality during the Gulf War.** Two epidemiologic studies have been completed on service member deaths that occurred during the Gulf War. One study reported on mortality during the six weeks from January 17, 1991 through February 28, 1991. It found that battle and nonbattle casualty rates were the lowest experienced by the United States in any major 20th century conflict.<sup>85</sup>

A more detailed mortality study covered the time period of August 1, 1990 through July 31, 1991, spanning the entire Operations Desert Shield/Desert Storm campaign and the post-war recovery.<sup>342,343</sup> This study examined the cause of each death and compared cause-specific mortality rates of troops in the Gulf region with those of U.S. troops serving elsewhere during this time period. Of the 372 deaths among active duty service members stationed in the region during this 1-year period, 147 (40 percent) were a direct result of combat, 194 (52 percent) resulted from nonbattle injuries, and 30 (8 percent) were the result of illness.\* An excess of unintentional injury (accident) deaths-e.g., from motor vehicle and aircraft accidents-was identified in the Gulf campaign participants compared to the nondeployed population. No excess mortality from illness or unexpected/undefined causes was observed, nor were there clusters of the deaths in timing or location.

**Mortality since the Gulf War.** A study of mortality among Gulf War veterans and a comparison population of era veterans since the Gulf War has been conducted by VA's Environmental Epidemiology Service.<sup>107,108</sup> Mortality among all 695,516 military personnel who served in Operations Desert Shield/Desert Storm between August 1990 and April 1991 was compared to 746,291 era veterans, adjusting statistically for branch of service, type of unit, age, sex, and race. During the study's timeframe (Gulf War through September 1993), 1,765 deaths occurred among Gulf War veterans, and 1,729 deaths occurred among the era veterans sampled.

Results of this study indicate that for the 2.4 years following the war, Gulf War veterans had significantly elevated mortality (nine percent higher) compared to era veterans. Excess fatalities were entirely attributable to external causes, including all types of accidents and, in particular, motor vehicle accidents. No excess of suicides, homicides, or deaths from disease-related causes was observed. The risk of death from infectious and parasitic diseases was significantly lower in Gulf War veterans.

When examined separately by sex, both men and women Gulf War veterans had a significant risk of mortality from external causes compared to era veterans. Mortality risks to both male and female Gulf War veterans from disease-related causes were similar and not significantly different from those of era veterans. When compared to the general population, both Gulf War and era veterans had significantly lower mortality rates when adjusted for age, sex, race, and year of death. This finding is consistent with findings in other military populations. Physical screening at entrance, continued standards for physical fitness, and access to medical care contributes to better survival rates among military personnel than observed in the age-matched population as a whole.

**Summary of mortality studies.** The completed mortality studies reveal no excess of deaths from natural causes during either Operations Desert Shield/Desert Storm or in the two years that followed. Death rates from all illnesses, including infectious diseases and cancers, have been the same or lower in the population deployed to the Gulf than those deployed elsewhere. Death rates from external causes have been elevated among Gulf War veterans.

Elevated mortality from external causes, particularly from motor vehicle accidents, is consistent with trends observed in populations of combat veterans from other wars. Studies of mortality in Vietnam veterans document an increased mortality rate from external causes such as injuries.<sup>21,257,290,326</sup> The mechanism underlying the excess deaths due to external causes among combat veterans is not well understood.

## **Morbidity Studies**

To answer fundamental questions about disease prevalence, epidemiologic studies must be



population-based, meaning they must draw information from samples representative of the entire population of interest. Little information is available from population-based studies on Gulf War veterans, although several studies are ongoing. For this part of the *Final Report*, we have reviewed findings from epidemiologic studies on Gulf War veterans' illnesses for which investigators have published results or publicly presented preliminary results and provided written abstracts. The studies undertaken most quickly after reports of illnesses in Gulf War veterans surfaced were investigations of clusters of reported illnesses or analyses of health databases of subgroups of the Gulf War veteran population.

**123d Army Reserve Command investigation.** In Spring 1992, an interdisciplinary team interviewed and examined 79 members of the 123d Army Reserve Command at Fort Benjamin Harrison, Indiana, after a number of members reported a variety of symptoms.<sup>41</sup> After physical and psychiatric examinations, the team found no evidence of an outbreak or cluster of any unique disease process. The most frequently reported symptom was fatigue (71 percent), which most commonly had its onset within several weeks of return from the Gulf. Physical examinations and laboratory screenings yielded limited positive objective findings similar to those seen in nondeployed soldiers. The group was self-selected, and therefore the results cannot be generalized to the larger Reserve or Gulf War veteran population.

**Seabee study.** A cluster study to investigate health complaints in Gulf War veteran reservists was carried out in the 24th Naval Mobile Construction Battalion between 1993 and 1994.<sup>10</sup> Two detachments, in which media reports had indicated a large degree of symptomatic illness, were evaluated with a standard questionnaire and a review of medical records to verify diagnoses and obtain additional information. No physical examinations or laboratory tests were performed. One year later, these detachments and two additional detachments were visited and surveyed again. Types and frequencies of diagnosed illnesses did not seem unusual for this age group, but no control group was analyzed. The symptoms did not suggest a pattern or particular illness to the investigators. As in the previously described study, the study group was self-selected, and therefore the results cannot be generalized to the larger Reserve or Gulf War veteran population.

**Study of women veterans.** A study on health symptoms in women Air Force Gulf War veterans was carried out with a survey questionnaire from 1991 to 1993; preliminary results have been presented publicly and await review for publication.<sup>199-201</sup> A randomized sample of Air Force women from the active duty, Reserve, and Guard were asked to report any conditions or symptoms for which they sought medical care since beginning service in the armed forces. The sample of 525 women included those deployed to the Gulf and those deployed elsewhere during the same time period.

The rates of baseline symptoms (i.e., those experienced prior to the Gulf War) did not differ between the two populations. However, results indicated a higher prevalence after the Gulf War of skin rashes, depression, unintentional weight loss, and headaches reported by those deployed to the Gulf compared with those deployed elsewhere. Reported health problems in general were higher in those deployed to the Gulf, and highest among those reporting they were no longer in the military.

A follow-up survey carried out between 1994 and 1995 on the same group also found higher levels of reported skin rashes and headaches among those deployed to the Gulf region. It also found increased reports of cough, memory problems, lumps or cysts in the breast, and abnormal Pap test results in Gulf-deployed women veterans. Differences between the two groups in reported depression, unintentional weight loss, and insomnia no longer were statistically significant. An additional follow-up survey is planned to see if reported differences persist.

Increases in self-reported health symptoms in this small, but representative, sample of Air Force women are consistent with the increased reports of health symptoms seen in cluster investigations. Since this study did not involve physical examinations or evaluate medical records, it cannot assess the extent to which increased concern or vigilance in Gulf-deployed service members could contribute to higher levels of reported signs and symptoms.

**Pennsylvania Air National Guard study.** CDC's National Center for Infectious Disease has carried out

a study of illnesses reported among Gulf War veterans in a Pennsylvania Air National Guard unit. This three-stage study began in late 1994 as a rapid response to reports of an outbreak of illnesses in the unit. At this time, findings from the first two stages have been published or presented publicly.<sup>211,291</sup>

The first stage involved standardized interviews and physical examinations of 59 Gulf War veterans reported to be symptomatic. Most frequently reported symptoms were fatigue, joint pain or stiffness, nasal or sinus congestion, diarrhea, gas, difficulty remembering, muscle pains, headaches, abdominal pain, general weakness, and impaired concentration. All study participants reported several symptoms that had persisted at least six months. No consistent abnormalities were identified through standardized physical examination or by review of medical records and laboratory tests.

In the study's second stage, unit members and three comparison units (a total of 3,927 individuals) were surveyed to determine the prevalence of selected symptoms identified in the first stage. In all units, the prevalence of 13 chronic (lasting six months or more) symptoms was significantly higher among individuals who had deployed to the Gulf.

The operational case definition developed for the illness in this population is similar to the definition for CFS recently developed by CDC, but lacks the requirement of severity of symptoms. Criteria for the case-as defined for the purposes of this study-were met in 45 percent of the veterans surveyed who had been deployed to the Gulf, but were also met in 15 percent of the nondeployed veteran respondents and in 12 percent of a San Francisco civilian population surveyed-suggesting the causes of the problems are not unique to Gulf War service. Symptoms were not associated with the place of service in the Gulf, number of deployments to the Gulf, or timing of deployment to the Gulf.

The study's final stage explored associations between having the symptoms defined in the study as being a "case" and selected infectious, behavioral, and environmental risk factors for developing the illness.<sup>212</sup> No physical or laboratory abnormalities were associated with being defined as a case. Despite the absence of physical findings, veterans who fit the definition of a severe case had measurable deficits in reported functioning. Veterans in this group also were more likely to meet screening levels for PTSD on the Mississippi Scale for PTSD. Data from this study stage are still preliminary and undergoing additional analyses.

Because the Pennsylvania Air National Guard study relied on volunteers who were a minority of the target population, the potential for bias exists in the research findings. Furthermore, the generalizability of the results from this study to the entire Gulf War veteran population is limited. Subjects were all members of the Air National Guard or Air Force and were not chosen to reflect the makeup of the larger Gulf War service member population.

**DOD hospitalization study.** The Naval Health Research Center in San Diego carried out a study of hospitalizations in military hospitals in the two years following the Gulf War.<sup>75</sup> Hospitalization frequency for 547,076 active duty Gulf War veterans was compared to that for 618,335 military personnel who did not go to the Gulf region. In the two years prior to the Gulf War, Gulf-deployed personnel were at lower risk of hospitalization than those not deployed. After the war, overall rates of hospitalizations in the two populations were similar. When examined by specific discharge diagnosis, Gulf War veterans were at elevated risk of hospitalization for some diagnoses, including testicular cancer and genitourinary disorders in 1991, diseases of the blood and blood-forming organs in 1992, and mental disorders during 1992 and 1993. The investigators found the differences were not consistent over time and concluded their results do not suggest an emerging illness associated with Gulf War service.

This study's results cannot be generalized to the Gulf War population at large because it only includes hospitalizations from active duty troops while they remained in the service. Members of the Reserves or National Guard, or those who left service, are not represented. Additionally, the study cannot provide information about types of illnesses that do not result in hospitalization. This research does, however, indicate the absence of a large increase in illnesses requiring hospitalization among active duty Gulf War veterans.

**Cognitive testing studies.** Some small epidemiologic studies have been carried out in Gulf War veterans to assess complaints of cognitive difficulties such as memory problems. Comprehensive, structured neuropsychological testing is used clinically to evaluate subtle cognitive difficulties. Typical dimensions that are evaluated by these tests include: intellectual functioning (i.e., estimated premorbid IQ), attention, concentration, language, visuospatial processing, learning/memory, and motor skills.<sup>316</sup>

Results of cognitive testing of four populations of Gulf War veterans have been published or presented at national medical conferences.<sup>73,120,316,318</sup> Although these four studies were small-groups of Gulf War veterans ranging in size from 19 to 149 people-several consistent findings emerge. On objective testing, memory and concentration performances were the same or only slightly decreased in groups of Gulf War veterans compared to control participants. Self-perceptions of memory dysfunction, however, were greater among the groups of Gulf War veterans. A small minority of Gulf War veterans who were significantly distressed due to PTSD or other psychiatric diseases did have objective memory and concentration impairment. These data are preliminary and require replication in additional studies.

**Summary of morbidity studies.** Completed morbidity studies show an increase in reporting of symptoms-such as fatigue, joint pain, memory problems, and headaches-in individuals who were deployed to the Gulf. The study results, however, do not indicate consistent abnormal laboratory or physical findings in these groups. Until results from some of the larger, population-based epidemiologic studies become available, conclusions cannot be generalized from these studies about the extent of illnesses in the Gulf War veteran population as a whole.

## DATA ON STRESS-RELATED DISORDERS

Physicians have observed in many previous wars that physical and psychological stress can lead to the development of higher rates of psychiatric illnesses than are observed in the general population. PTSD and depression are particularly prevalent problems in combat veterans. Stress is also known to affect the endocrine, cardiovascular, immune, and central nervous systems-i.e., to cause serious biological problems that are in no way trivial. As expected from experiences in previous wars, some Gulf War veterans report physical and psychological symptoms that frequently can be manifestations of stress, including fatigue, headaches, loss of appetite, sleep problems, and cognitive difficulties (such as memory problems and difficulty in concentration).

### Psychological Diagnoses in Clinical Programs

Psychological conditions are either the primary or secondary diagnosis in 36.0 percent of CCEP participants.<sup>277</sup> The most common conditions are: major depressive disorder, neurotic depression (also called dysthymia), depression (not otherwise specified), PTSD, anxiety disorders, adjustment disorders, alcohol-related disorders, and substance-related disorders (table 3-10).

Among participants in VA's Registry, 15.1 percent of the top three diagnoses for each patient were psychological conditions, with the most common being depression (not otherwise specified), PTSD, and anxiety disorders (table 3-10). Additionally, 15,486 Gulf War veterans had been admitted for treatment to a VA hospital as of September 1995, and psychological conditions were the most common diagnosis for these inpatients (43 percent of total diagnoses). Specific psychological conditions included PTSD and adjustment disorders, alcohol dependence, and drug dependence.<sup>109</sup>

The psychological conditions diagnosed among Gulf War veterans also are common in the general population. The best estimates of the prevalence of psychiatric disorders in the general population are based on the National Comorbidity Survey (NCS), a comprehensive, highly structured, population-based survey of 8,098 adults, aged 15 to 54 years.<sup>\*\*113,114</sup> The diagnostic criteria used in this national study are basically the same as that used by DOD and VA.

The percentage of individuals who met diagnostic criteria for several disorders in the 12 months preceding NCS interviews was: major depressive disorder, 10.3 percent; dysthymia (neurotic depression), 2.5 percent; generalized anxiety disorder, 3.1 percent; alcohol-related disorders, 9.7 percent;

and substance-related disorders, 3.6 percent.<sup>113</sup> The lifetime prevalence of PTSD was 7.8 percent.<sup>114</sup> Among the age groups encompassing 15 to 54 years, these serious psychiatric diseases peaked during 25 to 34 years; there was a significant decline in lifetime prevalence with increasing age.<sup>113</sup>

### **Treatment for Psychological Disorders**

Stress-related illnesses are real, often debilitating illnesses for which treatment interventions are available. Treatment for stress-related disorders is, by necessity, case-specific and symptom-oriented. For instance, no one treatment regimen is appropriate for the overlapping range of problems for tension headaches, chronic fatigue, fibromyalgia (FM), depression, and anxiety disorders. Despite some variability in therapeutic approaches to depression, anxiety disorders, and other psychological conditions, there is a relatively narrow range of treatment options.

Testimony before the Committee and interviews during site visits clearly indicate a significant stigma remains associated with psychological diagnoses. This perception often interferes with veterans receiving or accepting adequate care. In many instances, individuals report meeting command resistance to granting the necessary time off to maintain an adequate treatment program. This is true of all chronic illnesses, but especially so for veterans with psychological diagnoses—despite the fact that since 1986, service members with certain chronic illnesses that require medical monitoring have been allowed to remain on active duty.

Frank PTSD is particularly difficult to treat because alcoholism or other comorbidities frequently are present. Nevertheless, there has been some agreement on the basic approaches to treating PTSD. The Director of VA's National Center for PTSD describes three phases of treatment: stabilization/establishing trust and safety; trauma-focused therapy (therapy targeting the traumatic event), i.e., what happened and how one deals with and makes sense of what happened; and moving from the past to present reintegration into society by disconnecting from the trauma and reconnecting with the present.<sup>62</sup>

In randomized clinical trials, cognitive-behavioral therapy (CBT) has been the most successful treatment for PTSD. CBT centers on two psychological theories—learning theory and how one appraises a situation and develops a more adequate coping response. There are a variety of CBTs, including exposure therapies that include systematic desensitization, imaginal and *in vivo* exposure, and anxiety management training therapies (e.g., stress inoculation training, biofeedback, cognitive therapy, and relapse prevention). Often, exposure therapy and anxiety management are combined. CBTs can be used either individually or within group settings.

Several additional types of psychotherapy ranging from peer counseling to marital counseling to long-term dynamic therapy exist. Some are designed to be short-term and problem focused, while others are long-term and ongoing. Other disorders should be treated concurrently, although substance abuse usually must be treated first.

Some pharmacological treatments with drugs developed for depression (e.g., Prozac and Zoloft) also can be successful for PTSD. A fruitful area for research and development will be drugs that act on the neurobiological systems most implicated in PTSD and other stress-related disorders—e.g., corticotropin releasing factor antagonists, N-methyl-D-aspartate antagonists, and neuropeptide antagonists.

### **Stress-related Symptoms Reported in the Clinical Programs**

Headaches are a frequent symptom reported by Gulf War veterans who have received clinical evaluations through DOD and VA (39 percent of the top seven symptoms for CCEP and 18 percent of the top three symptoms in the Registry).<sup>109,277</sup> Tension headaches are coded under the diagnostic category "Psychological Conditions" and were diagnosed in 11.3 percent of CCEP participants and 2.3 percent of Registry participants. Other types of headaches are coded under "Nervous System Diseases" (migraine headaches) and "SSIDC" (nonspecific headaches). Migraine headaches were the primary diagnosis in 2.7 percent of CCEP participants, and nonspecific headaches were the primary diagnosis in

2.7 percent of this group. The frequency of headaches among Gulf War veterans does not appear to be unusual, since headaches are one of the most common reasons for seeking medical care.<sup>124,137</sup>

Gulf War veterans commonly report cognitive difficulties. These symptoms can be associated with diseases such as major depression and PTSD. For the CCEP, 34 percent of participants report memory loss and 27 percent report difficulty concentrating.<sup>277</sup> Fourteen percent of Registry participants report memory loss.<sup>109</sup>

To date, DOD reports that only a few CCEP participants have demonstrated cognitive deficits following neuropsychological testing. That is, such testing generally has eliminated an underlying neurologic etiology for the reported memory problems.<sup>277</sup> Organic brain syndrome (OBS) is a generic medical term for brain damage due to several diseases, such as head trauma or Alzheimer's disease. OBS is the primary diagnosis in 0.6 percent of the CCEP participants. The extent of OBS in the VA Registry population has not been reported.

The symptoms (i.e., diagnostic criteria) of common psychological conditions overlap with some of the symptoms that frequently are reported by Gulf War veterans. As noted earlier in this section, such conditions include major depression, PTSD, and anxiety disorder. As an example of the extent of overlap, diagnostic criteria for major depression are provided in table 3-11.<sup>3</sup> Comparison to table 3-2, which lists some of the symptoms frequently reported by the first 18,075 CCEP participants, reveals that symptoms relevant to major depression are: Criteria 1-depression (23 percent of CCEP participants); Criteria 4-sleep disturbance (32 percent); Criteria 6-fatigue (47 percent); Criteria 8-memory loss (34 percent); and Criteria 8-difficulty concentrating (27 percent). Criteria 3-weight loss was a frequently reported symptom for 7 percent of the first 18,075 CCEP participants.

### **Epidemiologic Studies of Stress-related Conditions**

The need to understand the effects of stress and related disorders in Gulf War veterans was recognized in 1991, and several epidemiologic studies focused on these issues were launched. Among the completed studies, the results primarily address the prevalence of stress-related conditions and the role of risk factors and protective factors.

**Large epidemiologic investigations on effects of stress.** Research targeted to increase knowledge about how stress could contribute to Gulf War veterans' illnesses involves several large-scale efforts. Studies with generalizable results are described briefly in the following sections. Other studies with similar, though not generalizable, results include the West Haven, CT, VA study of the 142nd medical unit and the 143rd military police unit of the Connecticut National Guard,<sup>239,240</sup> the Little Rock, AR, VA study of U.S. Army and Air National Guard and Reserve personnel,<sup>300,329</sup> and the Mountain Home, Johnson City, TN, VA study of the 24th Marines, Third Battalion, Company H.<sup>232-234</sup> Only one significant study has included large numbers of active duty troops-the Walter Reed Army Institute of Research (WRAIR) study of units from Pennsylvania and Hawaii.<sup>245-247,272</sup> Regrettably, the response rate in the WRAIR study was too low to extrapolate results to the overall Gulf War veteran population, but the study did find elevated rates of physical and mental distress among survey respondents who were deployed to the Gulf compared to those who were not.

**Fort Devens, Massachusetts VAMC.** Still in progress, the Fort Devens study involves 2,344 Gulf War veterans who have been followed by a research team at the Boston VAMC since 1991.<sup>334,337</sup> Comparisons between the study sample and the overall Fort Devens population indicated that the study subjects were representative of the military population that was processed through this base during that time. The study population included 46 units with a wide range of military occupational specialties from several regions in the United States. Hence, its results are relevant to the health status of the larger population of Gulf War veterans who were in the U.S. Army Reserve and National Guard.

Men and women in the Fort Devens sample had equivalent levels of combat exposure.<sup>336</sup> Fifty-six percent of both genders reported little or no direct combat exposure. However, if combat exposure was

held constant, certain types of stressors appeared to affect people differently. For women, witnessing death and serious accidents significantly predicted poorer psychological adjustment. For men, marital strife or being placed on chemical/biological alert or SCUD alert were more strongly associated with the development of psychological symptoms. Sexual assaults and harassment were the most important factors that explained the different rates of PTSD symptoms between women and men.<sup>334</sup> This group of veterans has been evaluated at three time points, starting with five days from their return.

Using the Mississippi Scale for Combat-Related PTSD, investigators found that approximately nine percent of women and four percent of men had PTSD-like symptoms that likely would qualify them for a positive diagnosis at Time 1 (five days after return).<sup>336</sup> At Time 1 and Time 2 (18 to 20 months after return), women reported more PTSD symptoms than men.<sup>337</sup> At Time 2, both men and women reported higher levels of PTSD symptoms than at Time 1 (11 percent for men and 21 percent for women). At Time 3 (approximately three years after return), however, rates of PTSD symptoms declined to approximate levels for Time 1, so there appears to be some recovery.<sup>334</sup>

To provide context for the rates of PTSD in Gulf War veterans, the best estimates of the rates of PTSD in the general U.S. population are based on the NCS, as described earlier.<sup>113,114</sup> Based on NCS data, lifetime prevalence of PTSD in men was five percent, and it was most commonly associated with combat experience during a war or witnessing someone being badly injured or killed. The lifetime prevalence of PTSD in women was 10.4 percent, and it was most commonly associated with a history of rape or sexual molestation.

During the follow-up examination at Time 4 (begun late 1996), actual functional status will be examined, such as days of work lost and quality of life. Continued funding for the Fort Devens study is being provided as part of the Boston VA Environmental Research Center. DOD recently funded a parallel study assessing psychological status in a group of Gulf War-era military personnel who did not deploy.

New Orleans, Louisiana VAMC. In 1991, the New Orleans VAMC developed a psychological assessment program as part of a series of programs set up at VAMCs nationwide.<sup>300</sup> The New Orleans research team evaluated 1,520 Reserve and National Guard troops who were mobilized for Gulf War duty. Because this larger study sample included Reserve and National Guard troops in the U.S. Army, Navy, Air Force, and Marines, study results are relevant to the health status of the larger population of Gulf War veterans who were members of the Reserve or National Guard.

The initial assessment took place within a few months of the end of the war.<sup>254,317</sup> Compared to nondeployed troops, individuals from deployed units reported more physical symptoms and had more negative mood states, including depression, anger, and anxiety. The two groups differed in prevalence of reported headaches, general aches and pains, lack of energy, and sleep disturbance. Twenty-three percent of war-zone-deployed troops reported at least mild levels of clinical depression, while 14 percent reported clinically significant levels of PTSD. Individuals diagnosed with PTSD also displayed less proficient cognitive performances in neuropsychological functioning, pertaining mostly to attention and new learning.<sup>317</sup> Deployed troops who reported higher levels of war-zone stress exposure were characterized by more depression, anxiety, anger, hostility, physical symptoms, and PTSD symptoms.

Women reported more physical symptoms than men, regardless of war-zone assignment.<sup>255</sup> Ethnic minorities reported more depression than nonminorities, regardless of war-zone assignment. No gender differences existed for measures of PTSD or psychological distress among deployed troops. Minorities among deployed troops were at greater risk for developing symptoms of PTSD than nonminorities among deployed troops.

Highland Drive (Pittsburgh) Pennsylvania VAMC. Starting in July 1991, the PTSD team at the Highland Drive VAMC in Pittsburgh conducted mental health screening and outreach programs for about 620 Reserve personnel from deployed and nondeployed units in the U.S. Army, Navy and Marines in western Pennsylvania, eastern Ohio, and West Virginia.<sup>197,300</sup> Because the study included individuals in

the U.S. Army, Navy, and Marines, results can be viewed in context of the larger population of Reserve personnel who served in the Gulf War. In addition, a wide variety of stressors were encountered by the units evaluated, ranging from simple unit activation for groups that stayed in the United States to the deaths and injuries suffered by the 14th Quartermasters (QM) Unit when its barracks were destroyed by a SCUD missile.

The 439 reservists who were deployed to the Gulf region demonstrated significantly higher rates of psychological symptoms than individuals sent to Europe or who stayed in the United States.<sup>197</sup> Gulf War veterans reported higher rates of PTSD, depression, and global psychological distress.

**Focused, small-scale epidemiologic studies on stress.** Researchers also have investigated stress responses in certain veterans who performed specific duties (e.g., graves registration) or experienced significant combat trauma (e.g., a SCUD missile attack). Because these research subjects experienced more extreme levels of stress than the average Gulf War veteran, data from these studies are not generalizable.

U.S. Army unit that experienced SCUD missile attack. The PTSD Clinical Team at the Highland Drive VAMC (Pittsburgh) developed an early treatment intervention program for the members of the 14th QM Detachment, whose barracks were destroyed by an Iraqi SCUD missile on February 25, 1991.<sup>198</sup> When the SCUD missile struck their barracks, 28 soldiers were killed, and 99 were wounded. Blast effects on survivors included extensive shrapnel wounds and ruptured eardrums.

The PTSD Clinical Team initially contacted members of the 14th QM during the week of March 18, 1991, and treatment continued until April 24, 1991. Five of the 20 soldiers who were onsite at the time of the missile attack were judged to have met the criteria for PTSD during the initial assessments. Testing revealed these soldiers reported distress from nearly twice as many symptoms related to war stress as the four soldiers who had been on guard duty three miles away at the time of the attack. Nine of these 24 soldiers reported an increase in their alcohol consumption since their return home.

At the end of treatment, the 20 soldiers who had been onsite showed significant decreases of symptoms related to PTSD and depression. One patient was judged to continue to meet full criteria for the diagnosis of PTSD, while the other four patients who previously had met the PTSD criteria were still showing significant, though decreased, stress symptoms. Alcohol consumption was reported as decreased for most of those interviewed.

A follow-up study of the 14th QM in 1993 revealed about half of the treated patients were continuing to show improvement, and about half of the patients were returning to pretreatment levels of symptoms.<sup>204</sup> The PTSD team at the Highland Drive VAMC continues to follow and treat the surviving members of the 14th QM.

U.S. Army units that performed graves registration duties, New Orleans VAMC. Among the sample of 1,520 military personnel studied by the New Orleans VA, were 194 members of QM units assigned graves registration duties that encompassed handling, identification, and processing of bodies and body parts. In one unit (24 people), investigators found the prevalence of PTSD was 46 percent. They also reported a high incidence of psychiatric diagnoses concurrent with PTSD, including depression (33 percent) and alcohol abuse/dependence (13 percent).<sup>252</sup>

A second study compared 40 service members who performed graves registration duties with 20 individuals from the same units who were not deployed to the Gulf War and who did not perform graves registration duties.<sup>253</sup> Current diagnoses of PTSD were made in 48 percent of the deployed troops, compared to none for nondeployed service members. Diagnoses concurrent with PTSD included depressive disorder (18 percent) and alcohol dependence (10 percent). After one year, 42 percent of the service members who had performed graves registration continued to meet criteria for PTSD.<sup>317</sup> The New Orleans research team continues its followup of both groups who performed graves registration duties.



U.S. Army units that performed graves registration duties, Walter Reed Army Institute of Research. Researchers at WRAIR's Department of Military Psychiatry also studied units with graves registration duties. They found consistent, but milder, symptoms compared to the New Orleans groups.<sup>152,153</sup>

**Summary of epidemiologic data on stress.** Epidemiologic studies to assess the effects of stress invariably have found higher rates of PTSD in Gulf War veterans than among individuals in nondeployed units or in the general U.S. population of the same age. It also appears groups with the most severe stress, such as the group injured by the missile attack, have a greater risk of PTSD than other Gulf War veterans.

In the large epidemiologic studies performed in Boston and New Orleans, the rates of PTSD and other psychological conditions had increased at the one-year follow-up evaluation, rather than ameliorating over time. Long-term followup to determine the effectiveness of treatment and outreach efforts is indicated in these study groups. The long-term effects of stressors of the Gulf War on active duty troops remain largely unexplored.

## **DATA ON UNDIAGNOSED ILLNESSES**

A significant number of Gulf War veterans who have participated in the government's clinical programs report symptoms that do not fall into standard diagnostic categories. The epidemiologic studies also have identified many veterans who report symptoms of illness, but who do not show abnormalities on physical examinations or standard diagnostic tests. Congress has authorized VA to provide disability compensation to Gulf War veterans with undiagnosed illness (Public Law 103-446; 38 CFR 3.317), but the impetus to determine the underlying cause of the problem remains.

### **Data from Clinical Programs**

More than 40 percent of CCEP participants have a primary or secondary diagnosis of SSIDC. This diagnostic category includes an extremely heterogeneous group of miscellaneous symptoms that do not fit elsewhere in the diagnostic coding system. As shown in table 3-12, the category encompasses generalized symptoms, such as malaise and fatigue; isolated abnormal laboratory results (i.e., a nonspecific reaction to the tuberculin test or an elevated sedimentation rate); and symptoms that prove to be transient (e.g., an episode of seizures or a rash, by history only).<sup>277</sup> No significant anatomical, physiological, biochemical, or pathological abnormalities are detectable in individuals whose symptoms are coded in the SSIDC category. DOD has reported that the frequency of symptoms coded under SSIDC for CCEP participants is about five times higher than the frequency of coding of SSIDC in the general U.S. population aged 20 to 40 years.<sup>277</sup>

Of VA's Registry participants, 10,391 individuals (19.9 percent) reported some symptoms, but they did not have a characteristic set of signs and laboratory test abnormalities that allowed a medical diagnosis to be made.<sup>109</sup> This group of Registry participants is comparable to the group of CCEP participants who were coded with a primary diagnosis of SSIDC, and their symptoms are similar. Table 3-13 presents the most common symptoms among these VA participants.

### **Symptom-based Diagnoses**

The Committee noted the interest of many veterans in possible links between unexplained illnesses and recognized diagnoses—such as CFS and FM—that are based on symptoms reported by the patient rather than on physical abnormalities evident to a physician or on laboratory findings. Veterans also expressed a need to know more about Multiple Chemical Sensitivity (MCS), which is not currently a recognized diagnosis in U.S. medical practice.

**Chronic Fatigue Syndrome.** The CDC's 1994 consensus case definition for CFS requires both:

- Clinically evaluated, unexplained, persistent, or relapsing fatigue for at least six months that is of new or definite onset; is not the result of ongoing exertion; is not substantially alleviated by rest;



and results in substantial reduction in previous levels of occupational, educational, social, or personal activities. In practical terms, most CFS patients are unable to work full-time.

- Four or more of the following concurrent symptoms on a persistent or recurrent basis during six or more consecutive months of illness, none of which may predate the fatigue:
  - self-reported impairment in short-term memory or concentration severe enough to cause substantial reduction in previous levels of occupational, educational, social, or personal activities;
  - sore throat;
  - tender cervical or axillary lymph nodes;
  - muscle pain;
  - multi-joint pain without joint swelling or redness;
  - headaches of a new type, pattern, or severity;
  - unrefreshing sleep; or
  - postexertional malaise lasting more than 24 hours.<sup>63</sup>

The 1994 CDC case definition lists many medical and psychiatric conditions that exclude the diagnosis of CFS. CFS is strictly a diagnosis of exclusion, and no confirmatory lab test exists.<sup>63</sup>

The prevalence of CFS in Gulf War veterans is unknown. VA diagnoses patients with CFS, but it has not reported the proportion of veterans in the Registry with this diagnosis. DOD has reported that 42 of the first 10,020 participants in the CCEP (0.42 percent) met the 1994 CDC case definition for CFS; 278 of its report on 18,075 participants did not provide this information.

**Fibromyalgia.** The 1990 American College of Rheumatology consensus case definition of FM requires both:

- chronic widespread pain in all four quadrants of the body ("pain all over"); and
- pain in at least 11 of 18 tender point sites on digital palpation.<sup>333</sup>

Other symptoms FM patients frequently report include sleep disturbance, fatigue, morning stiffness, anxiety, headache, and depression. No exclusions are made for the presence of concomitant X-ray or laboratory abnormalities. Therefore, a patient may be diagnosed with FM and another disorder simultaneously, such as rheumatoid arthritis, osteoarthritis, or major depression. There is no confirmatory lab test.

The prevalence of FM in Gulf War veterans is unknown. VA diagnoses patients with FM, but it has not reported the proportion of veterans in the Registry who have FM. DOD has reported that approximately 1.5 percent of CCEP participants have received a primary or secondary diagnosis of FM.<sup>277</sup>

**Multiple Chemical Sensitivity.** There is no consensus case definition for MCS, although two recent government-sponsored conferences have attempted to develop one. MCS patients report many symptoms, including tiredness or lethargy, fatigue, memory difficulties, difficulties concentrating, dizziness or lightheadedness, and depressed feelings when exposed to low levels of common, everyday substances. Symptoms relevant to many different organ systems have been linked to MCS in the clinical ecology literature; symptoms related to the central nervous system are the most common.

The majority of patients diagnosed with MCS have no objective abnormalities on physical examination or on routine laboratory testing. The physicians who use this diagnosis use a variety of nontraditional diagnostic and treatment techniques, none of which have been validated in a controlled trial.

One physician who specializes in MCS has consulted on 75 patients at the Houston VA Persian Gulf Referral Center. She reported that among her first 59 consultations, 46 patients (78 percent) reported a variety of symptoms, referred to as intolerances, when exposed to various chemical inhalants such as traffic exhaust, perfume, or tobacco smoke.<sup>160</sup> No other data on chemical intolerances in Gulf War veterans exist.

**Overlap of symptom-based diagnoses.** Several studies have demonstrated that symptoms of CFS, FM, and MCS overlap. A 1994 Seattle study evaluated three groups with 30 patients each who had been diagnosed with CFS, FM, or MCS. Researchers for this study concluded that symptoms typical of each disorder were prevalent in the other two conditions and that, "with the exception of tender points, other physical examination findings appear to be prominent by their absence in CFS, FM, and MCS."<sup>19</sup> The symptoms of CFS, FM, and MCS also are common among CCEP and Registry participants with undiagnosed illness. The government is sponsoring research on each of these conditions.

**Deficits in peripheral nerve function.** At least one researcher has suggested a link between unexplained illnesses among Gulf War veterans and measurable deficits in peripheral nerve function attributable to one or more Gulf exposures.<sup>29</sup> The publication, however, reports on a small population that was not randomly selected, so data are not generalizable to the entire Gulf War service population. Reported results also revealed no objective differences between Gulf War veterans and civilian participants, and there was no evidence for a clinically demonstrable peripheral neuropathy in any of the Gulf War veterans who participated in the study.

## ILLNESS AMONG FAMILY MEMBERS

Some veterans and their family members, scientists, and physicians have voiced concern that Gulf War veterans' illnesses could or do affect the health of their families. The potential for adverse reproductive outcomes-infertility and birth defects-and new hypotheses regarding communicable diseases have generated the most anxiety.

### Data from the CCEP

Since CCEP's inception in 1994, spouses and children of active duty personnel have been eligible for enrollment. DOD's April 1996 report discussed its evaluation of 332 spouses and 191 children.<sup>277</sup> VA began a similar program for the spouses and children of veterans in April 1996. As of November 1996, about 1,500 individuals had enrolled in the VA program, but the clinical results had not been reported.

Table 3-14 reports the frequency in CCEP of the primary and all diagnoses in the 332 spouses.<sup>277</sup> Overall, the distribution of diagnoses in spouses is similar to the distribution of the diagnoses in enlisted individuals. The most prevalent major diagnostic categories are psychological conditions, MSDs, and SSIDC. The genitourinary system is one organ system that has substantially higher rates of diseases in spouses, who largely are women-not surprising as this is a finding also typical in women in the general U.S. population aged 20 to 40 years, when compared to men the same age.<sup>222</sup>

Primary diagnoses for the 191 children in DOD's CCEP are shown in table 3-15.<sup>277</sup> Seventy-two children were healthy. Thirty-five children were born with various congenital anomalies that were not concentrated in a single organ system. Seventeen children had skin problems of the types that are common in the general U.S. pediatric population. The remaining 67 children were diagnosed with a range of diseases in several organ systems. As with the adult CCEP population, results from analyzing data collected from this population-a self-reported case series-cannot be generalized to the entire Gulf War population.

### Adverse Reproductive Outcomes

In the years after the Gulf War, media reports based primarily on anecdotal evidence asserted increased rates of birth defects in children born to Gulf War veterans. Reports of high levels of infertility and pregnancy loss also appeared in the national press. Among the difficulties in assessing whether Gulf War veterans were experiencing these problems because of their service, is the fact that reproductive failures are common occurrences in the United States.

Physicians diagnose major birth defects in three to four percent of infants in the first year of life. A birth defect is a structural abnormality present at birth, including malformations, which involve poor tissue formation; deformations, which involve abnormal changes in developing tissue; and disruptions, which

involve the breakdown of normal tissue. Major birth defects are those that affect survival, require substantial medical care, or result in marked physiological or mental impairment.

Birth defects are the leading cause of infant mortality in the United States, accounting for more than 21 percent of all infant deaths. Of the approximately 100,000 to 150,000 infants born with a major birth defect each year, approximately 6,000 die during the first 28 days of life, and an additional 2,000 babies die before reaching their first birthday. Annually, then, 92,000 to 142,000 children affected to various degrees by birth defects live beyond the first year.<sup>16,179</sup>

More than one in eight couples in the United States is classified as infertile, defined as the inability to conceive after trying for 12 months. In addition, approximately 20 percent of pregnancies end in spontaneous abortion (miscarriage) between the 4th and 28th week of pregnancy. However, estimates of total pregnancy loss that include figures derived from studies prior to the fourth week of pregnancy conclude that as many as 75 percent of all conceptions are lost-often without the woman ever knowing she was pregnant.<sup>28</sup>

The causes of birth defects, in general, can be determined in just over half of all cases.<sup>143</sup> In the vast majority of cases, birth defects occur in families where there is no history of the disorder. The reasons for infertility and pregnancy loss also are often difficult to impossible to elucidate.

To evaluate potential associations between Gulf War service and adverse reproductive outcomes, the Committee undertook two primary tasks: an appraisal of the biological plausibility of such an association and an assessment of government studies in this area. (In chapter 2, the Committee evaluated government services that are relevant to addressing reproductive health-related clinical needs and concerns of veterans. We analyzed reproductive health risks of specific Gulf War exposures in chapter 4 as part of our analyses of health effects on all organ systems.)

**Biological plausibility.** Many things can go wrong in a pregnancy. In fact, many scientists posit that it is miraculous that most often children are born healthy. Determining the causes of adverse outcomes is a complex process. To establish an environmental exposure as the cause of a birth defect, there must be a valid, even if hypothetical, explanation as to how a particular agent or agents could have acted biologically to produce a particular effect.

**Teratogenicity.** Teratogens are environmental agents that adversely affect the fetus in the uterus. Exposure to teratogens accounts for three percent of all birth defects. Over the past 30 years, a significant amount of data have been collected on the reproductive risks of exposing pregnant women to infectious agents, drugs, chemicals, and physical environmental agents (i.e., ionizing radiation or heat). The use during the 1960s of thalidomide by pregnant women and the resulting limb reductions in their children serves as a prime example.

It is likely that some teratogens were present in the KTO. In part to protect fetuses from potential exposure to teratogens, pregnancy was cause for either nondeployment or evacuation from the theater.<sup>309</sup> There are no known reports of birth defects in children born to women who were pregnant with them while they were in-theater.

Teratogens to which males are exposed throughout conception and pregnancy, such as those reported in certain occupational settings, potentially could affect the developing fetus. An embryo or fetus could be exposed either by transfer of the teratogen via the semen during intercourse or by exposure of the pregnant woman to the toxic agent via the clothing of the male.<sup>194</sup> However, exposures unique to the Gulf War environment are highly unlikely to have affected children via this male-mediated mechanism.

**Mutagenicity.** Toxic agents that cause mutations are called mutagens. Mutagens act on either somatic cells (the cells of the body) or germ cells (eggs and sperm), or both. Their actions on germ cells are distinct from the effects of teratogens because they alter the genetic constitution of the germ cells prior to conception. Ovarian exposure to some mutagens can disrupt the ovarian cycle and damage the oocyte, resulting in potential infertility, fetal loss, or birth defects. Because females receive a fixed amount of

oocytes before birth, chronic or long-term exposures to ovarian mutagens can have a cumulative and permanent effect on the health and vitality of ova.

In contrast, the effects of mutagens on male reproductive biology most often are transient, although a few agents are known to be stem cell mutagens or remain for long periods in the body. Males manufacture millions of sperm daily in a cyclical, constantly renewing process of cell division. The adverse effects of mutagens are likely to dissipate in 90 days-the time required for complete turnover of sperm-after the exposure ends. If conception were attempted within that 90-day period and the exposure had a mutagenic effect, infertility or pregnancy loss would be the most likely outcome. Either the sperm would be too damaged by the mutagen to fertilize the egg, or the sperm would contribute to the creation of an embryo that carried too many mutations to survive beyond a few days. In a few documented exposures (such as cancer patients exposed to high doses of radiation and chemotherapy), sterility can be permanent because of damage to the stem cell pool.<sup>225</sup> It is possible that some types of nonlethal mutations to stem cells may result in birth defects.<sup>56</sup>

Some veterans and advocates have hypothesized a connection between exposure to mutagenic agents in the Gulf and development of Goldenhar syndrome in veterans' offspring. Decades of research have revealed that mutagenic agents are not specific.<sup>16,78</sup> Current evidence is such that a mutagen would be expected to cause a random increase in the incidence of genetic disease, not the increase of particular genetic syndromes to the exclusion of others.

Data available concerning the types and levels of exposures that occurred during the Gulf War do not indicate the presence of potent mutagens, particularly agents that would affect stem cells.<sup>17,134</sup> It is known that mustard agent, as a carcinogen, has mutagenic properties (i.e., it affects the somatic cells of the exposed individual), but it is unlikely the effects of low-level exposure would manifest as birth defects. Infertility would be the more likely reproductive outcome, cancer in the individual exposed the most likely long-term outcome.

The mechanisms of male reproductive biology make it unlikely that acute exposures to environmental agents present in Southwest Asia would result in adverse reproductive outcomes. Under the circumstances surrounding possible exposures to males in the KTO, an increase in a single type of birth defect is biologically implausible. If there were demonstrable adverse effects related to exposure, infertility or reduced fecundity are the most expected outcomes.

**Studies of reproductive health of Gulf War veterans.** In addition to establishing biological plausibility, epidemiologic studies are necessary to determine whether a connection exists between exposure experiences while in the Gulf and subsequent adverse reproductive outcomes. If such an association exists, two outcomes of epidemiologic studies would be expected.

First, a higher overall prevalence of adverse outcomes-including birth defects, infertility, pregnancy loss, stillbirth and prematurity-than would be expected in the normal population should be demonstrated. If approximately 200,000 children are born to Gulf War veterans, approximately 6,000 to 8,000 congenital malformations would be expected based on general population risks.

Second, if an association with a teratogen (not a mutagen) exists, one might see an unusual cluster of a specific type of birth defect appearing across multiple independent studies. Should either of these results occur, investigators could then work backward to evaluate whether there is some commonality among those who are affected-e.g., living in the same geographic location, similar ethnicity, or common exposures of the fetus to drugs, illness, or environmental agents.

Even with sophisticated epidemiologic studies, however, caution must be exercised. Any epidemiologic study dealing with all birth defects invariably will find some birth defect occurring at an increased incidence-i.e., a cluster-in the study population.

Researchers can assess and monitor approximately 60 major birth defect outcomes. In a properly designed protocol that encompasses an appropriately large sample size, one would expect that three birth

defects would appear to be substantially increased, just by chance alone. In other words, any single epidemiologic study of birth defects in children of any cohort is likely to reveal-based on chance alone-a cluster of defects unrelated to exposure. In fact, it has been argued that if a properly designed epidemiologic study of birth defects does not result in a statistically significant cluster, this finding in and of itself would be particularly noteworthy.

Thus, before a cluster can be validly linked to an exposure, additional investigations of similar, but distinct, populations must be conducted to determine if a similar cluster is again observed. Only by surveying the total relevant population (which is usually prohibitive for practical and economic reasons) could one be absolutely certain of determining the true prevalence rate. Moreover, as noted earlier, biological plausibility also must be assessed.

Well-designed, scientifically valid epidemiologic studies comparing events among a random sample of Gulf War veterans to an appropriate group are required to determine whether an association exists between Gulf War service and the risk of adverse reproductive outcomes. The government's initial attempts to study the prevalence of birth defects in the children of Gulf War veterans showed mixed, nongeneralizable results. For example, slightly elevated rates of birth defects were found in a self-reported population surveyed by VA, but no increased prevalence of birth defects was found in a study of the children of National Guard members from Mississippi.<sup>195</sup> To date, the government has sponsored three studies that should yield some generalizable, though limited, results.

Record-based evaluation of the risk of birth defects and military service in the Gulf War. In 1994, DOD funded a record-based evaluation of the risk of birth defects and military service in the Gulf War (known as Study 3). Although the study has a number of design deficiencies, it still is notable that researchers found that risks of birth defects-whether broadly or narrowly categorized-were not different among the deployed and nondeployed groups (using an adjusted odds ratio).<sup>37</sup>

Survey of reproductive outcomes. Another DOD-sponsored project (known as Study 4) aims to determine whether Gulf War veterans are experiencing partial or total infertility or other adverse reproductive outcomes at rates greater than would be expected. Experiences of a total of 16,000 couples will be compared for different reproductive experiences: married couples in which the woman served in the Gulf during the war; married couples in which the man served in the Gulf during the war; married couples in which the woman served in the military during the war but not in the Gulf; and married couples in which the man served in the military during the war but not in the Gulf. The survey, which is still underway, has been plagued by a low response rate.

Prevalence of congenital anomalies among children born to Gulf War veterans. A third study (often referred to as Study 7) has been designed to determine whether the prevalence and types of major congenital anomalies among children born between January 1, 1989 and December 1993 differ among Gulf War veterans, nondeployed military personnel, and civilians; among active duty and separated veterans; and among pre- and post-deployment conceptions. It will describe any patterns of major birth defects revealed and compare rates of fetal death, low birth weight, and pre-term deliveries. This study has considerable design advantages over previous studies assessing the reproductive health of Gulf War veterans.

A substudy of this investigation involves an evaluation of the prevalence of oculoauricularvertebral spectrum (Goldenhar syndrome) among children born or hospitalized in DOD medical treatment facilities. To date, five cases of Goldenhar have been identified among offspring of 34,067 Gulf War veterans, and three cases were identified among offspring of 41,220 nondeployed veterans. Although the rate per 100,000 of the Gulf War veteran group is seemingly twice that of the nondeployed group, the difference is not statistically significant.<sup>189</sup>

**Absence of baseline data.** One problem that plagues all studies of reproductive outcomes among Gulf War veterans is the absence of baseline data on military populations. The birth defects surveillance programs operated and coordinated by CDC have helped to diminish this problem in the civilian sector. The primary purpose of the National Survey of Family Growth, performed by the National Center for

Health Statistics (NCHS), is to collect national data on factors affecting pregnancy and birth rates in the United States. NCHS has conducted the survey five times since 1973 and uses widely accepted sampling and survey methods to estimate rates of infertility, pregnancy loss, and birth defects. The samples are representative of the civilian noninstitutionalized population of women aged 15 to 44. Selected, proximate risk factors that might affect infertility and pregnancy loss also are collected.<sup>28</sup>

In addition to being used to search for increases in the incidence of specific malformations, surveillance systems can be used to develop baseline data, provide timely rates, identify geographic areas of concern for cluster investigations, and provide the basis for ecological investigations and follow-up studies to identify causes or risk factors such as drugs, nutritional factors, environmental exposures, maternal illnesses, and genetic factors.<sup>143</sup> No such baseline data collection system specific to the reproductive health of military personnel currently exists.

**VA program for spouses and children.** In April 1996, VA established the Examination Program for Spouses and Children of Persian Gulf Veterans to fulfill a congressional mandate (Public Law 103-446). This program could eventually yield some data about reproductive outcomes among the families of Gulf War veterans. Under this authority, VA may provide examinations to any individual who: is the spouse or child of a veteran who is listed in VA's Registry and is suffering from illnesses or disorders; is suffering from, or could have suffered from, an illness or disorder (including a birth defect, miscarriage, or stillbirth) that cannot be disassociated from the veteran's service in the Southwest Asia theater of operations; or has granted VA permission to include in the Registry relevant medical data from the evaluation.

The program initially was funded at \$2 million and was to be open to the first 4,500 individuals who called VA's Helpline. It has been extended through 1998. Examinations are provided by university-affiliated physicians at 32 VAMC coordinating centers, and participants are examined at one of these contractor sites. The program does not pay for travel or reimburse for incurred expenses. Examinations of spouses are similar to VA's Phase I Registry examination, including a standardized history and physical examination. The protocol for the children of veterans involves a detailed medical history, including symptoms and a developmental history. VA is not authorized to provide medical followup or treatment of conditions diagnosed by the medical examination. The program currently is not designed to provide useful research results, but could be used to identify areas needing further evaluation.

### Infectious Diseases

Infectious diseases are a special concern to Gulf War veterans and their family members. Based on its CCEP, DOD reports no clinical evidence that Gulf War veterans have transmitted an infectious disease endemic to the Gulf to their spouses or children. Among 332 spouses of veterans who have been evaluated, 23 individuals (7.0 percent) have a primary or secondary diagnosis of an infectious disease (table 3-14).<sup>115</sup> These include 14 cases of fungal skin infections, six cases of vaginal yeast infections, two cases of warts, and one case of tuberculosis—all of which are common infectious diseases in the general U.S. population.

Among 191 children of Gulf War veterans who have been evaluated in the CCEP, 17 children (8.9 percent) have a primary diagnosis of an infectious disease (table 3-15).<sup>277</sup> Nine children have an upper respiratory infection, six children have otitis media (ear infection), one child has tinea capitis (fungal skin infection), and one child has chronic pneumonia. All of these diagnoses are common childhood infectious diseases in the general U.S. population, with the exception of chronic pneumonia.

Three other microorganisms have been hypothesized as possible etiologies for illnesses in some Gulf War veterans and their families: *Mycoplasma* infections, microsporidia infections, and occult, systemic streptococcal infections. Each hypothesis awaits systematic, controlled research to confirm it as a potential cause of morbidity in Gulf War veterans.

- Dr. Garth Nicolson, a cancer researcher, has suggested that many symptomatic Gulf War veterans

have illness caused by *Mycoplasma fermentans* (*incognitus* strain),<sup>182</sup> resulting in a broad range of symptoms and organ dysfunctions that encompass nearly every system.<sup>183</sup> A systematic description of the symptoms, abnormalities on physical examination, or abnormalities on routine testing for patients believed to be infected with this organism has not been presented, and so a case definition is not possible. CDC has approached Dr. Nicolson about funding a case-controlled study to evaluate *Mycoplasma* presence in the Pennsylvania National Guard unit study described earlier.<sup>11</sup> As of December 1996, Dr. Nicolson has continued to defer this collaborative research.

- In 1995, a microbiologist at the VAMC in Mountain Home, TN, reported he found small round bodies, which he identified as microsporidia, in the stool specimens of some Gulf War veterans. Microsporidia are parasites that can cause diarrhea and wasting.<sup>328</sup> Following his report, VA collected several stool specimens along with gastrointestinal (GI) biopsy material from individuals identified as having a positive histochemical stain. The samples were evaluated by experts at several institutions; no microsporidia-like organisms or other known intestinal protozoans were detected in the stool samples, and the histology of the GI material was normal. In addition, CDC found no evidence of microsporidia among the stool specimens from subjects in the Pennsylvania National Guard unit study.<sup>12</sup>
- Dr. Edward Hyman, a primary care physician in New Orleans, states he has diagnosed a streptococcal bacteremia that he calls "systemic coccal disease," in about ten Gulf War veterans and ten of their family members.<sup>92-94</sup> He describes this syndrome as manifesting "almost universally as chronic fatigue, but with pains in muscles and fibrous tissue or FM, with nerve and mental findings, neuritis and brain loss, with lung impairment, with arthritis of one kind or another, with skin rashes that usually itch, with blood changes, etc." Dr. Hyman has treated the Gulf War veterans and their families, and he reports that, initially, all veterans improved noticeably, but most of them soon relapsed. No research approved by an institutional review board has been initiated on this hypothesis.

Based on available evidence, the Committee believes it is unlikely these microorganisms are responsible for widespread disease among Gulf War veterans or their families.

## SUMMARY

In the absence of generalizable, quantitative information about the extent of Gulf War veterans' illnesses, only a qualitative range of symptoms and illnesses being reported by Gulf War veterans can be described. This general picture derives from information about participants in DOD's and VA's clinical evaluation program and preliminary data from several epidemiologic studies.

The Committee believes the most significant findings about the nature and extent of Gulf War veterans' illnesses-and recommendations for followup-must await the conclusion of the population-based epidemiologic studies. These results will come in well after the Committee disbands. Still, extensive information about many aspects of Gulf War illnesses exists. Based on in-house expert consultations, literature reviews, briefings, and testimony, the Committee makes the following findings and recommendations.

## FINDINGS

- Gulf War veterans have experienced no excess mortality from natural causes during or after the war. Gulf War veterans have experienced excess mortality from external causes, such as injuries, which is consistent with the experience of veteran populations from previous conflicts.
- Information from the clinical programs indicates musculoskeletal conditions and ill-defined conditions are common components of Gulf War veterans' illnesses.
- Data from the clinical programs and epidemiologic studies indicate stress-related disorders are common components of Gulf War veterans' illnesses.
- Among the subset of the Gulf War veteran population examined in the ongoing clinical and research programs, many veterans have illnesses likely to be connected to their service in the Gulf. Currently, the extent of service-connected illness in the population is unknown.
- Stigmatization of psychosomatic illness seriously interferes with some veterans seeking care.

- It is unlikely that exposures in the Gulf War theater are responsible for the birth defects of children born to veterans.
- VA's examination program for spouses and children of Gulf War veterans has little or no value as a research program and offers no incentive for participation, thus raising expectations about the government's ability to respond to health care needs in veterans and their families that are impossible to meet.
- The absence of baseline data regarding the reproductive history and health of military personnel makes determinations of the effects of exposures during deployment more complex and difficult.

## RECOMMENDATIONS

- Research on possible causes and methods of prevention of excess mortality from external causes among veterans should receive high priority.
- Research on Gulf War veterans' illnesses should emphasize investigating the causes and methods of prevention and treatment of musculoskeletal conditions.
- Research on Gulf War veterans' illnesses should emphasize investigating the causes and the methods of prevention and treatment of stress-related disorders.
- Since the stigmatization of mental illness continues to be a problem for society at large, DHHS should place a priority on developing public education outreach programs that note the indissoluble association between the mind and the body. DOD and VA should make a special effort to address and target such needed educational outreach to their communities.
- Since Congress has extended VA's examination program for spouses and children of Gulf War veterans, VA should formulate what it intends to do with the results and consider mechanisms to reimburse travel and other costs.
- The government should consider methods for routinely sampling military populations regarding reproductive health so that an appropriate baseline exists for evaluating reproductive outcomes following deployment. In particular, DOD should consult with the National Center for Health Statistics and strongly consider implementing its National Survey of Family Growth and related methodologies for collecting data.

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\*The cause of one death was unknown. Since this paper was published, some of these casualties have been reclassified. The current official count of deaths from hostile action in Operation Desert Storm is 148 person.

\*\*Participants were not selected from a treatment-seeking population, but were asked whether they had recently sought medical care.



## **Presidential Advisory Committee on Gulf War Veterans' Illnesses Final Report**

### **Chapter Four**

## **GULF WAR RISK FACTORS**

U.S. service members potentially were exposed to a broad range of risk factors during the Gulf War. The Committee evaluated the potential health effects of several suspected risk factors, which were selected based on our charter, previous reports on Gulf War veterans' illnesses, and expert and stakeholder testimony at meetings held nationwide. We also have attempted to analyze the extent and likelihood of exposure to these risk factors during the Gulf War. In most instances, however, exposure data have been difficult to obtain or nonexistent. This chapter reports the Committee's findings on the following risk factors:

- pesticides,
- chemical warfare agents,
- biological warfare agents,
- vaccines,
- pyridostigmine bromide,
- infectious diseases,
- depleted uranium,
- oil-well fire smoke,
- petroleum products, and
- psychological and physiological stress.

The chapter first reports what is known currently about possible U.S. troop exposure to each risk factor. Following this analysis, we discuss health effects known to date, and we present our findings and recommendations in the final section of this chapter.

### **EXPOSURE TO RISK FACTORS IN THE GULF**

As described in the Committee's *Interim Report*, few exposure data exist on many key Gulf War risk factors. In fact, for most of the risk factors we analyzed, the only exposure information available today is anecdotal recollections of Gulf War veterans. As a consequence, it will be difficult to link, in a scientifically valid manner, any adverse health outcomes detected by ongoing research to specific exposures or risk factors. As noted in chapter 2, the Committee has concluded that DOD's Persian Gulf Registry of Unit Locations will be of little use for investigating questions about Gulf War veterans' health issues and is certainly an inadequate substitute for missing exposure data.

#### **Exposure to Pesticides**

Precise records exist for pesticides DOD shipped to the Gulf region (table 4-1). All pesticides shipped were approved by EPA or FDA for general use in the United States at the time of the Gulf War. U.S. consumers can purchase these at grocery, gardening, and other stores in products such as: OFF® and Cutters® (DEET), Raid® Ant and Roach Killer Spray and Raid® Yard Guard (permethrin), Black Flag® Insect Spray (Baygon), permethrin spray for treating clothes, and a variety of Ortho® brand and other name brands of gardening products containing carbaryl, diazinon, malathion, chlorpyrifos, and permethrin.

While DOD can document what pesticides were shipped-and how much-there are virtually no records available today on how these pesticides were used in the Gulf region. DOD made no provisions for collecting or keeping distribution or use records of U.S.-shipped and approved products. Reports from a few veterans about the use of other, locally obtained, unapproved pesticides are impossible for the Committee to followup.

Assuming DOD adhered to its policies on pesticide use, its programs closely parallel those established by EPA and FDA regulations for domestic pesticide use. According to DOD policy, the majority of U.S. service members had access to two pesticides: permethrin in a spray can (for treating uniforms) and DEET liquid or stick as a personal mosquito and fly repellent. DOD reports about 2.2 spray-cans of permethrin and 2.0 tubes of DEET (33 percent formulation) were shipped to the Gulf for each U.S. service member. According to DOD, U.S. troops were not provided with permethrin pretreated uniforms. All other pesticides shipped to the Gulf region were to be used only by specifically trained individuals or for special applications. For example, lindane apparently was used nearly exclusively on Iraqi prisoners of war as a delousing agent.

### **Exposure to Chemical Warfare Agents**

DOD has fully acknowledged one case of CW agent exposure. U.S. Army Sergeant Fisher was exposed to a small amount of mustard agent while patrolling an Iraqi bunker during the war. Diagnosis was made on the basis of small chemical burns on his arms consistent with mustard exposure.<sup>52</sup> DOD also has confirmed nerve agent detections by Czech units, but has identified neither sources nor potentially exposed U.S. troops.<sup>13,119</sup> DOD has confirmed release of nerve agent at Khamisiyah in March 1991, and the Committee has concluded that troops near the demolition activity should be presumed to have been exposed to some level of nerve agent (see chapter 2). The Committee does not presume, however, that this implies long-term health effects in those exposed. DOD continues to investigate other reported CW agent detections.

Except for the Fisher incident, DOD reports in-theater medical surveillance observed no immediate or characteristic poisoning symptoms from any exposure to CW agents. According to representatives from the U.S. Army Medical Corps, which was responsible for training medical personnel to be alert during the war for signs and symptoms of CW agent exposures, characteristic poisoning from nerve agents such as sarin and soman were not seen by medical personnel during the Gulf War.<sup>52</sup> At least one other DOD medical repre

sentative, however, posits that a presumption of low-level exposure to OP nerve agents should be made when evaluating unexplained medical problems reported by some Gulf War veterans.<sup>13</sup>

### **Exposure to Biological Warfare Agents**

Based on classified and public information currently available, the Committee has concluded there is no persuasive evidence that U.S. troops were exposed to BW agents during the Gulf War.<sup>35,51,52,119,148,274</sup> We note our determination is based on imperfect information. For instance, the United Nations cannot verify the quantities and weaponization status of Iraqi BW products because Iraq claims it unilaterally destroyed all its biological weapons. Additionally, the United States did not deploy a real-time BW agent detection system during the war.

Two salient factors, however, led to the Committee's conclusion. First, there were no verified detections of anthrax or botulinum toxin during the war. Second, stateside examination of soil samples and enzyme assays did not reveal the presence of BW agents. The Committee's review of U.S. Army hospital admissions records identified one admission for anthrax (a disease indigenous to the Gulf region) and none for botulinum poisoning.<sup>342,343</sup> DOD has investigated reports of dead animals that might have succumbed to biological agents, and we concur with the finding that the evidence does not implicate BW agents. Finally, UNSCOM reported to the Committee that Iraqi officials have denied any use of biological weapons during the war and that its own assessment supports this claim.

### **Exposure to Vaccines**

DOD estimates approximately 150,000 U.S. military personnel received at least one anthrax vaccination, and about 8,000 service members received at least one dose of BT vaccine during the Gulf War. As noted in the Interim Report, however, medical recordkeeping on these and other matters was woefully inadequate.

## Exposure to Pyridostigmine Bromide

All U.S. troops received blister packs containing PB pills during the Gulf War. The pills were intended to be self-administered upon a unit commander's order. DOD estimates approximately 250,000 personnel took at least some PB during the Gulf War.<sup>118</sup> As noted in the Interim Report, accurate assessment of PB exposure of U.S. troops is not possible today because no records were kept of self-administered medications.

## Exposure to Infectious Diseases

Infectious diseases endemic to the Gulf region include shigellosis, malaria, sandfly fever, and cutaneous leishmaniasis.<sup>6,65,90,187</sup> Along with

these infectious diseases, DOD medical personnel also monitored troops for dengue, Sindbis, West Nile fever, Rift Valley fever, and Congo-Crimean hemorrhagic fever.<sup>90,293</sup>

According to DOD, no cases of sandfly fever were reported during Operations Desert Shield/Desert Storm. Medical personnel saw seven individuals with malaria, one with West Nile fever, and none with rickettsial or other arthropod-borne viral illnesses; arthropod-borne viral diseases endemic to the Gulf are not known to cause chronic infection or disease. The documented low rates of infection among U.S. troops suggest exposures were minimal and/or preventive measures were effective.

## Exposure to Depleted Uranium

According to the Office of the Army Surgeon General, 36 U.S. service members are known to have been exposed to DU when wounded in "friendly fire" incidents involving DU munitions.<sup>112,267</sup> VA reports it believes about two dozen of these individuals retain embedded DU shrapnel in their bodies.

In addition to exposure through "friendly fire" incidents, a review by the U.S. General Accounting Office concluded that several dozen service members were exposed to DU while retrieving or servicing vehicles damaged by DU munitions.<sup>267,306</sup> This number comprises about two dozen Army National Guard soldiers from the 144th Service and Supply Company who have reported they were unknowingly exposed to DU-contaminated debris while working with combat vehicles hit by DU munitions. Another two dozen soldiers from the 24th Infantry Division have reported they were unknowingly exposed to such debris in the course of vehicle recovery and maintenance operations.<sup>96,97,267,306</sup>

Although DOD had appropriate procedures for protecting personnel who worked with DU contaminated vehicles during the Gulf War, apparently few U.S. service personnel were adequately trained in these procedures. U.S. service personnel also could have been exposed to DU if they inhaled DU dust particles during incidental contact with vehicles destroyed by DU munitions, or if they lived or worked in areas contaminated with DU dust from accidental munitions fires. Thus, unnecessary exposure of many individuals could have occurred.<sup>15,18,20,27,42,44,57,141,142,161,186,191,203,226,260,267,306</sup>

With the exception of individuals who retain embedded DU munitions fragments, it is not possible to use *in vivo* monitoring today to develop accurate assessments of DU exposure in the Gulf. Whole-body counting to detect photons of x-ray or gamma radiation cannot be used to test for DU: The equipment is not designed to detect the low energy photons associated with DU decay.<sup>87</sup> Moreover, the time that has elapsed since the Gulf War is long compared to the body's retention rate of uranium-i.e., it would be difficult to detect DU even with more sophisticated equipment performing specialized tests such as lung counts.<sup>87,259</sup>

## Exposure to Oil-well Fire Smoke

In contrast to other risk factors, exposure to oil-well fire smoke is better characterized. Many U.S.

service members who remained in the Gulf after the oil well fires started could have been exposed to oil-well fire smoke. The burning wells were located in eastern Kuwait, with the majority to the south of Kuwait City. Smoke plumes rose and combined in a "superplume" that could be seen for hundreds of kilometers and sometimes even partially blocked out the sun. Occasionally, smoke plumes touched down to the ground, sometimes enveloping nearby troops. Exact exposure levels for individual soldiers are not certain, but local and regional exposure information is available for oil well fires.

Multiple U.S. and international agencies performed extensive air monitoring during the fires and did not find pollutant levels likely to cause long-term health effects:

- A U.S. Interagency Air Assessment team-comprised of scientists from EPA, the National Oceanographic and Atmospheric Administration, and DHHS-arrived in Kuwait in March 1991 to assess the potential health effects of the oil well fires.<sup>311</sup>
- Scientists from 12 countries, including Kuwait and neighboring countries, were involved in a data collection effort overseen by the World Meteorological Organization.<sup>339</sup>
- The U.S. Army's Environmental Hygiene Agency carried out the largest effort, collecting nearly 4,000 ambient air and soil samples from May to December 1991.<sup>265</sup>

The data indicate that, despite the dramatic appearance of the oil plumes, pollutant levels were surprisingly low. All groups found that levels of nitrogen oxides, carbon monoxide, sulfur dioxide, hydrogen sulfide, other pollutant gases, and polycyclic aromatic hydrocarbons (PAHs) were lower than anticipated and did not exceed those seen in urban air in a typical U.S. industrial city.<sup>89,289,302,339</sup>

High levels of airborne particulate matter (sand and soot), however, were observed frequently at several monitoring sites. Analysis of samples suggested particles were mostly sand-based materials; high levels of airborne sand particulates are typical for this region of the world. Within the samples of particulate matter, levels of PAHs and toxic metals were low.<sup>84,265</sup>

Samples were collected during at least one instance when the smoke plume had touched down, providing "worst case" exposure data. Although airborne contaminants were detectable, they were surprisingly low compared to current U.S. occupational standards for these contaminants-even within the plume touchdown.<sup>84,265,266</sup>

Various biological samples also were collected from troops or other personnel working in Kuwait while the fires burned. One CDC study found blood levels of volatile organic compounds (VOCs) in firefighters were significantly higher than those in a U.S. reference population,<sup>55</sup> but individuals in Kuwait City, about 20 km from oil fires, had VOC levels approximately that of the reference group. These data are limited by small sample size and the short half-life of VOCs in service members' blood, but they suggest oil-well fire smoke did not significantly increase VOC exposures in troops in the Kuwait City area when most of the fires were active.

Blood and urine samples collected from a group of U.S. service members before, during, and after their 1991 deployment to Kuwait were analyzed for VOCs, PAH-DNA adducts, metals, and sister chromatid exchange (SCE) frequency in lymphocytes.<sup>265</sup> Pulmonary function tests and questionnaires also were administered. Levels of metals, VOCs, and PAH-DNA adducts showed no changes or showed decreases in troops living in Kuwait compared to troops living in Germany, with few exceptions. Lead levels in blood were not statistically significantly altered during deployment to the Gulf region.\*

### Exposure to Petroleum Products

Few specific data exist about possible exposures of U.S. service members to petroleum fuels or their combustion products. Operating the vehicles and machinery used in the Gulf War involved exposure to petroleum-based material. Petroleum fuels also were used for burning wastes and trash, dust suppression, and fueling stoves and tent heaters; none of these uses is unique to the Gulf War. Such uses, however, probably led to increased petroleum vapor and combustion product exposures. Thus, some U.S. service members were exposed to petroleum materials, including benzene, toluene, xylene, ethyl

benzene, and combustion products including carbon monoxide, sulfur dioxide, nitrogen dioxide, particulates, lead, and other pollutants.

The U.S. Army's air monitoring (and blood monitoring done by CDC in a small study) found no evidence of elevated exposure to VOCs (including petroleum materials).<sup>55,265</sup> Still, some service members clearly experienced short-term, elevated exposures to petroleum fuels. For example, diesel was sprayed on the ground to suppress dust from the fine sand found in the Gulf region. A U.S. Central Command document lists crude oil/waste oil as the least desirable option for dust suppression, but does not mention diesel fuel.<sup>280</sup> One U.S. Army sanitary engineer testified to the NIH Technology Assessment Panel in 1994 that units used water or diesel fuel for dust suppression during the war.<sup>100</sup> He described one brigade dumping 30,000 gallons of diesel fuel on the roads daily, and said U.S. service members living in tents near the roads-and particularly truck drivers carrying out the spraying-complained of nausea from breathing the resulting fumes. As a result, the preventive medicine person to whom they complained obtained respirators for the drivers' use.<sup>101</sup> Another occupational group that could have experienced some risk of elevated exposures to petroleum products during the Gulf War were those who worked at military "Petroleum, Oils, and Lubricants" points where these materials were distributed.

The fuel used most widely during the war for both vehicles and equipment was Jet A-1, an internationally used kerosene-based aviation fuel provided at no cost by the Saudi Arabian government. Of the 1.8 billion gallons of fuel used during Operations Desert Shield/Desert Storm, roughly 75 percent was jet fuel (mostly Jet A-1), 24 percent was diesel fuel, and 1 percent was gasoline.<sup>248</sup> The gasoline used during Operations Desert Shield/Desert Storm was commercial leaded gasoline refined to Saudi Arabia's national standard.<sup>135</sup>

Combustion products from heaters used in poorly ventilated areas also are a general exposure concern for Gulf War participants. Burning leaded fuels indoors without proper ventilation-e.g., heaters in tents-could have caused increased lead exposure. Kerosene heaters, widely used in the United States, also could have been significant sources of exposure to nitric oxides, sulfur dioxide, inorganic combustion gases, carbon monoxide, and particles when used with inadequate ventilation.<sup>165</sup> During the war, four hospitalizations in U.S. Army field hospitals occurred because of asphyxiation from carbon monoxide.<sup>342,343</sup>

### **Exposure to Psychological and Physiological Stress**

U.S. service members encountered many stressors during the Gulf War, including short deployment notice, uncertainty about length of deployment, isolation and separation from family, a polluted environment, poor living conditions with little privacy or social outlets, prolonged work hours, decreased income and worry about job retention, fear of SCUD missile and chemical and biological weapon attacks, anticipation of high casualty rates and torture, frequent CW agent alarms that often required a defensive posture and full chemical gear, and dealing with casualties and dead bodies.

Even when the war was over, many veterans experienced postdeployment stress on their return from the Gulf. These included financial and employment difficulties, unresolved military pay issues, the revelation of cases of leishmaniasis and the consequent temporary ban on blood donations, increasing numbers of health complaints and "unexplained illnesses," and media accounts of apparent increased numbers of birth defects and cancer.

### **HEALTH EFFECTS OF GULF WAR RISK FACTORS**

The Committee undertook a comprehensive analysis of the health effects of the ten Gulf War risk factors for which we examined possible exposures. Our analysis of possible health effects was performed independently of whether exposures were undocumented, imprecise, or known. That is, we considered the possible health consequences of a range of scenarios from high-level to low-level exposure and from single to multiple event and chronic or continuing exposure. The Committee also considered short-term

and long-term health effects, including symptoms that might have appeared while service members were still in the KTO and symptoms that might not have appeared until sometime after the service members left the Gulf. The Committee's search for possible health effects extended to all organ systems and to cancer and noncancer outcomes.

Our examination of health effects drew on three types of sources: scientific literature; briefings and workshops with recognized experts; and information presented at Committee meetings. The Committee reviewed human exposure (mostly occupational) data and laboratory animal data. We found extensive scientific literature describing the human health effects for all the risk factors investigated, including CW agents, for which we initially had anticipated would have significant data gaps. The breadth and depth of information generally were sufficient\*\* to make conclusions about the short- and long-term health effects that would be anticipated for U.S. service members exposed to a particular risk factor during the Gulf War. The information available in these sources, however, represents the boundaries of the Committee's investigation. We conducted no primary research and elected not to base our findings on research not yet subjected to peer review.

Finally, the Committee drew conclusions about the role of each risk factor in Gulf War veterans' illnesses based on comparison of the known health effects of the risk factor to the symptoms reported by Gulf War veterans. Symptoms reported by Gulf War veterans used in these comparisons were based on DOD's CCEP and VA's Persian Gulf Health Registry (see [table 3-2](#)).

## Pesticides

As noted earlier in this chapter, pesticides DOD shipped for use during the Gulf War fell into five major categories: OP pesticides, methyl carbamate pesticides, organochlorine pesticides (lindane), pyrethroid pesticides (chiefly permethrin), and DEET.

**Organophosphorus pesticides.** Several OP pesticides were used during the Gulf War, including chlorpyrifos, diazinon, dichlorvos, and malathion. When administered in high doses, OP pesticides cause irreversible inhibition of acetylcholinesterase, an enzyme crucial to normal nerve and nerve/muscle function. Inhibiting acetylcholinesterase leads to unique and highly characteristic poisoning symptoms. Immediate symptoms of OP poisoning in humans usually develop within four hours of exposure and include narrowing of the pupil of the eye (miosis), headache, nausea, dizziness, anxiety, and restlessness. Severe and rapid onset poisoning symptoms include muscle twitching, weakness, tremor, incoordination, vomiting, abdominal cramps, diarrhea, sweating, salivation, tearing, runny nose, and production of phlegm. Life-threatening symptoms include unconsciousness, incontinence, convulsions, and depression of breathing function. According to DOD, its medical monitoring and surveillance efforts reported no cases of immediate and severe OP poisoning symptoms in U.S. military personnel during the Gulf War.

Some individuals who recover from immediate and severe OP poisoning show long-term (lasting more than a year), subtle, neuropsychological abnormalities that can be detected using a battery of standardized neuropsychological tests. In an epidemiologic study of such long-term effects, severely poisoned individuals showed clear but subtle differences in intellectual functioning, academic skills, abstraction and flexibility of thinking, and simple motor skills. For example, about a five point difference in IQ was measured in severely poisoned versus control subjects.

Neurophysiologic effects were less apparent; abnormalities were found only in measurements of memory, abstraction, and mood and on one test of motor reflexes.<sup>221</sup> These effects could not be detected, however, in a subset of the same worker population that had been exposed to doses of OP pesticides that were too low to cause the symptoms of immediate and severe poisoning.<sup>241</sup> Other studies of low-level occupational exposures reinforce the finding that these types of long-term effects present solely in the aftermath of severe and immediate OP agent poisoning.<sup>4,241</sup>

Some OP pesticides that are no longer sold in the United States have been associated with human cases of a second type of delayed toxic effect called organophosphate-induced delayed neurotoxicity (OPIDN, sometimes referred to as delayed neuropathy). Initial symptoms are muscular incoordination progressing to numbness, tingling, fatigue or a cramp-like pain in the calf muscles, and even moderate to severe

muscular weakness and paralysis.<sup>7,117</sup> Typically, effects occur 7 to 14 days following recovery from immediate and severe poisoning by the OP pesticide and involve neuropathologic lesions and degeneration of the nerve axon and myelin nerve sheath in both the central and peripheral nervous systems;<sup>117</sup> these effects are easy to measure in a clinical setting. In general, OPIDN caused by OP pesticide poisoning is associated with immediate poisoning symptoms.

All OP pesticides sold in the United States today are routinely screened for OPIDN toxicity with a standardized hen assay used by EPA; the hen is a laboratory animal especially sensitive to OPIDN effects. For some OP agents, these effects only can be observed by giving the hen extremely high doses that would rapidly lead to death, but then keeping the hen alive through the use of protective drugs such as atropine. Many investigators conclude any OP agent theoretically could cause this effect at sufficiently high doses, but that, in fact, immediate toxic effects cause death before delayed effects can be seen.<sup>117</sup> None of the pesticides DOD shipped to the Gulf War test positive for OPIDN in standard EPA screens.

**Methyl carbamate pesticides.** Methyl carbamate insecticides shipped for use during the Gulf War included propxur (Baygon®), carbaryl (Sevin®), and methomyl (Lannate®). These insecticides reversibly inhibit acetylcholinesterase, which leads to poisoning effects similar to OP poisoning. Poisoning with methyl carbamates tends to be of much shorter duration-with a greater margin of safety between symptom-producing and lethal doses-compared to OP pesticides, which bind permanently with acetylcholinesterase.

**Pyrethroid pesticides.** DOD shipped the pyrethroid insecticide permethrin to the Gulf for use as an insect repellent. Permethrin is used widely in the United States as the active ingredient in personal care products, such as shampoos and lotions, and for treating clothes to make them insect repellent. There are few reported poisonings of humans by permethrin, most likely because such a large dose is required to cause poisoning. Humans rapidly detoxify and excrete permethrin. Clinical signs of immediate permethrin poisoning following large oral doses become evident within two hours and include incoordination, ataxia, hyperactivity, and convulsions, followed by prostration, paralysis, and death.<sup>171</sup> Unlike OP pesticides, the Committee found no reports of long-term effects from permethrin poisoning in humans.

A National Research Council (NRC) subcommittee that reviewed possible health problems for military personnel wearing permethrin-treated military clothing concluded it is unlikely that soldiers using such uniforms would experience adverse health effects at the suggested exposure levels. The subcommittee concluded, "the weight of evidence shows that permethrin is unlikely to be a skin irritant or skin sensitizer for military personnel who are exposed to it dermally from wearing permethrin impregnated [uniforms]." The estimated "no observable adverse effect level" for immediate neurotoxic effects in humans from daily exposure is 200 milligram (mg)/kilogram, which is approximately three million times greater than estimated dermal exposure from permethrin treated uniforms.<sup>171</sup> NRC's worst-case estimate of lifetime carcinogenicity risk for humans wearing permethrin treated uniforms was less than 2 in 1,000,000.

In laboratory animal studies, dermal absorption of permethrin is low, although scientists observe neurotoxic effects if the substance is injected.<sup>171,301</sup> Most, but not all, studies have reported permethrin does not cause damage to genetic material in a wide variety of standard measurement systems. Permethrin is neurotoxic to laboratory animals at high oral doses. Rats fed permethrin at 6,000 mg/kg for 14 days showed fragmented and swollen sciatic nerve axons and myelin degeneration. However, nerve conduction studies in 23 permethrin workers showed no evidence of nerve impairment associated with permethrin exposure.<sup>171</sup> Rodent bioassays of chronic exposure to permethrin showed carcinogenic effects, such as liver and lung adenomas and lung carcinomas in mice, but data on human carcinogenicity of permethrin are lacking.

**Organochlorine pesticides.** DOD shipped one organochlorine pesticide, lindane, to the Gulf region. Lindane, once widely used as an agricultural insecticide in the United States, is still available as a lotion

to treat head and body lice and scabies.<sup>283,301</sup> Lindane is dermally absorbed, stored in body fat, and only slowly leaves the body. Reports document that a few people who have used large amounts of lindane on their skin have had blood disorders and even seizures. Under conditions of extremely high exposure, lindane can cause liver and kidney disease.

Some pregnant laboratory animals orally treated with the maximum tolerated dose (the dose just below that causing immediate and severe toxicity) showed a statistical increase in the number of fetuses with extra limbs, indicating that lindane is a teratogen for this laboratory animal strain. Lindane has not been shown to be a human carcinogen, although long-term oral exposure of lindane to certain species and strains of laboratory rodents has been reported to cause liver cancer.<sup>283</sup> Hence, DHHS has determined that lindane should be viewed as a human carcinogen.

**DEET.** DEET, first introduced in 1955, continues to be a widely used liquid insect repellent in the United States, and DOD shipped approximately two 2-oz tubes per U.S. service member during the Gulf War. According to EPA, 50 to 100 million Americans use DEET-containing insect repellents annually. Relative to most pesticides, DEET has notably low immediate toxicity.<sup>190,301</sup> Although generally well tolerated when used as an insect repellent applied to human skin, about five to nine percent is absorbed through skin, and reports exist of tingling, mild irritation, and occasional skin peeling following repeated application.<sup>301</sup> Topically applied DEET is rapidly eliminated, mostly in the urine. In the past 35 years a few reports in the medical literature suggest rare neurotoxic effects.<sup>190</sup> In adult humans, ingestion of enormous doses of DEET has been associated with immediate toxic effects, including tremors, generalized seizures, and coma, although no long-term effects of poisoning have been reported.<sup>320</sup> (For possible synergistic effects, see section on PB later in this chapter.)

Rats continuously fed DEET up to the maximum tolerated dose over three generations showed a slight increase in the high-dose animals in a single neurological abnormality—a slight increase in exploratory locomotor activity—and no histopathologic central nervous and peripheral nervous system changes of significance.<sup>190</sup> Other reports indicate that rats fed the maximum tolerated dose of DEET can show severe and often fatal prostration accompanied by a brain myelinopathy.<sup>320</sup>

**What do we conclude about the risks of pesticides to Gulf War veterans?** According to DOD, after-action reports from in-theater medical personnel did not reveal any U.S. troops reporting symptoms that would indicate pesticide poisoning. Evidence from studies of humans poisoned by OP pesticides suggests that low-level exposures that do not cause signs and symptoms of immediate and severe poisoning will not result in long-term health effects. Thus, the Committee concludes it is unlikely that health effects and symptoms reported today by Gulf War veterans are the result of exposure to pesticides during the Gulf War. Lindane is an animal liver carcinogen, but it is too early to see an elevated liver cancer rate in Gulf War veterans.

## Chemical Warfare Agents

At the time of the Gulf War, the U.S. military believed Iraq had weapons that could deliver OP nerve agents, including sarin, soman, and VX, and mustard (blister) agents. Hence, U.S. forces were supplied with protective gear, detectors, and prophylactic drugs to protect against the known consequences of exposure.

**Immediate signs and symptoms of nerve agent poisoning.** OP nerve agents are designed to incapacitate and kill humans. Inhalation exposure to these agents leads to immediate effects, including miosis, runny nose, and increased salivation. Immediate effects following skin exposure include local sweating and muscle twitching. Eye exposure rapidly produces miosis, which often is associated with eye pain, headache, and blurred vision.<sup>264</sup> In fact, miosis is the most sensitive and specific immediate response to acute poisoning in humans, and this reaction has served as the basis for establishing allowable occupational concentrations for CW nerve agents. Higher doses of these agents cause more severe effects, including convulsions, neuromuscular blockage, profuse airway obstruction and apnea-developing within one to two minutes of exposure.<sup>77</sup> Death occurs due to respiratory paralysis.



The effects of nerve agent poisoning (figure 4-1) are virtually identical to those of severe OP-pesticide poisoning.

Data on human effects of CW nerve agent poisoning derive largely from human experiments carried out by the U.S. Army from the 1940s to the 1960s. Table 4-2 illustrates the type of information on immediate poisoning effects from low-level exposures to the OP nerve agent sarin.

**Immediate signs and symptoms of mustard agent poisoning.** With mustard agents, poisoning symptoms are severe irritation and tissue damage to eyes, skin, and respiratory and gastrointestinal (GI) tracts. Usually the onset of symptoms is delayed for some hours after exposure.

One report of Iraqi use of mustard agent against Iranian troops in 1984 documented health effects in more than 5,000 Iranian casualties. Affected individuals had first to third degree burns over 20 to 70 percent of the total skin surface. Eye exposure caused tearing, severe conjunctivitis, and temporary loss of vision. Corneal abrasion was nearly always present, and photophobia and blurred vision developed in some cases. Upper airway involvement due to chemical burning of the throat led to pharyngitis and tracheobronchitis. These effects were quite severe, and this group suffered approximately 15 percent mortality. Those who survived the initial symptoms later experienced various GI complaints, including nausea, vomiting, and diarrhea. After five to seven days, hematologic problems were the greatest health threat to survivors.<sup>105</sup>

**Long-term health effects of exposure to CW nerve agents.** Two NRC reports addressed possible long-term morbidity and mortality in about 1,400 servicemen intentionally exposed to CW nerve agents in experiments conducted over a 20-year period ending in 1975. The possibilities of excess cancer risk and adverse mental, neurologic, hepatic, and reproductive effects were reviewed. Both NRC analyses concluded that no evidence exists that CW nerve agents cause long-term, adverse human health effects at the doses tested. The doses were nonlethal, but were high enough to cause clinical effects (such as miosis). NRC reported that both analyses had the power to detect any major health effects had they been present. A statistically significant increase in admissions to VA hospitals for malignant neoplasms was detected, with the caveat that admission numbers were small, showed no dose relationship, and no clustering of specific chemicals in relation to tumor site.<sup>174,175</sup>

Numerous studies in humans and animals report that survival from severe, immediate poisoning by OP nerve agents (including OP pesticides) can be associated with measurable, long-term neurological effects. One study of 77 industrial workers exposed to levels of sarin that caused immediate toxicity showed slight alterations in electroencephalograms (EEGs) one year after exposure. The study also reported, however, that trained experts could not distinguish an individual EEG from an exposed individual from an EEG of a person who had not been exposed, and that no clear relationship existed between alterations in EEG frequency spectrum and alterations in brain function.<sup>22</sup> A 1975 review by Lohs of the effects of CW agents in humans similarly reported long-lasting effects following severe, immediate OP pesticide and CW agent poisoning.<sup>140</sup>

CW nerve agents do not show OPIDN toxicity as measured in EPA's standardized hen bioassay for evaluating OP pesticides, except with extremely high doses (10 to 100 times the lethal dose) where immediate and severe toxic effects, including death, are seen.<sup>117</sup> Because OP CW nerve agents are chemically similar to OP pesticides and affect the same enzyme system in the body, similar long-term health effects would likely occur in the aftermath of immediate, severe poisoning with sarin, soman, or VX-i.e., the subtle, but measurable, neurophysiological and neuropsychological effects described earlier in this chapter. Again, these health effects did not occur in populations that had been exposed to subclinical amounts of OP pesticides. Current scientific evidence suggests that subclinical exposure to OP CW nerve agents does not result in long-term neurophysiological and neuropsychological health effects. Ongoing research at the Boston and Portland Environmental Hazards Research Centers is investigating the possibility of such effects in Gulf War veterans.

**Long-term health effects of exposure to mustard agents.** Based on epidemiologic research, humans exposed to mustard agent are at increased risk for lung cancer.<sup>98,287</sup> Several other reviews of human

exposure to mustard agent during World War I (WWI) and other wars also indicate veterans exposed to mustard agents during the Gulf War could experience other respiratory problems as well.<sup>98,287</sup>

During World War II (WWII), more than 60,000 U.S. service members were used as human test subjects and exposed to mustard agents, including at least 4,000 individuals exposed to high concentrations of these agents.<sup>28</sup> An Institute of Medicine (IOM) review concluded that several specific chronic diseases are causally associated with mustard agent exposure. These include various respiratory cancers, skin cancer, chronic skin ulceration and scar formation, chronic respiratory disease including asthma, chronic bronchitis, emphysema, chronic eye diseases, and various psychological disorders including PTSD. IOM also found suggestive evidence (weaker than the associations for the conditions just mentioned) that exposure to mustard agent was associated with leukemia. Finally, IOM also analyzed two studies that examined the link between mustard and reproductive dysfunction, but determined that the database could not be used to make conclusions about human reproductive health effects.<sup>98</sup>

**What do we conclude about the risks of CW agents to Gulf War veterans?** Current scientific literature indicates that when exposure to OP CW agents results in immediate and severe poisoning, long-term, subtle neuropsychological and neurophysiological effects could occur. Available scientific evidence does not indicate that such long-term effects occur in humans following low-level exposures, but the amount of data from either human or animal research on low-level exposures is minimal. Long-term effects in humans exposed to mustard agents include an elevated risk of lung cancer beginning decades after exposure. Based on available data, it is unlikely the health effects reported by Gulf War veterans today are the result of exposure to OP or mustard CW agents during the Gulf War. Ongoing or planned federally-funded studies focused specifically on low-level exposures and delayed neurotoxicity of CW agents should elucidate gaps in knowledge and eliminate uncertainty and/or identify new directions for research.

### **Biological Warfare Agents**

The U.S. military prepared for the possibility that Iraq might use two BW agents-anthrax and botulinum toxin-against U.S. service members during the Gulf War. After the war, new data revealed Iraq had also weaponized aflatoxin. The Committee evaluated the potential health effects of these three BW agents on the long-term health of Gulf War veterans.

**Anthrax.** Anthrax is a bacterial disease most often found in cattle and sheep. Human infection can occur by contact with infected animals or by inhalation of spores from infected animal products (e.g., as hides or wool). Left untreated the disease usually is fatal. After exposure, the anthrax bacteria travel to the intestines and other areas where they cause severe tissue damage. Initial symptoms include nonspecific malaise, low grade fever, and nonproductive cough. Initially, anthrax can be difficult to diagnose because symptoms, although severe, are not specific.<sup>103</sup> As the disease progresses, symptoms include high fever, labored breathing, choking cough, and vomiting; death usually occurs within four days.<sup>276</sup> Terminal symptoms include abrupt onset of shortness of breath, harsh breathing, skin turning blue, excessively rapid heartbeat, and rapid progression to shock and death. Cases of pulmonary anthrax caused by inhalation of aerosolized spores (which would be the case in a military use) are almost invariably fatal if not treated immediately with antibiotics. Exposure to small numbers of infecting spores can increase the incubation time of the disease from a few days to several weeks, but if infection occurs, the disease progresses toward death in the same manner as for high-level exposure.<sup>103,276</sup> No long-term effects have been reported in persons successfully treated for anthrax.

**Botulinum toxin.** Botulinum toxin is a group of related, highly poisonous protein agents isolated from fermentation of the bacterium *Clostridium botulinum*, which naturally occurs in soil and can grow in many meats and vegetables. Botulinum toxin is fast-acting, usually producing symptoms within 18 to 36 hours after ingestion. Death occurs in 80 percent of an exposed population after one to three days.<sup>276</sup> Botulinum toxin blocks neuromuscular conduction by binding to receptor sites on motor nerve terminals and by inhibiting the release of acetylcholine. Symptoms at high exposure levels can include respiratory distress and respiratory paralysis, which may persist for six to eight months.<sup>117</sup> Disability progresses

from difficulty in walking and swallowing and impaired vision and speech to convulsions. Ultimately, symptoms include paralysis of the respiratory muscles, suffocation, and death-all within a few hours or days, depending on the amount of toxin ingested.<sup>276</sup> In cases of accidental exposure in the general population, the fatality rate is 35 to 65 percent and is fatal in three to ten days.<sup>117</sup> Botulism antitoxin can be effective if administered within days of exposure.<sup>276</sup> The Committee found no scientific literature suggesting adverse long-term health effects from low-level exposure to botulinum toxin.

In fact, botulinum toxin has conventional medical therapeutic uses. Botox® is an FDA-approved, purified, type A botulinum toxin, and injecting it into the muscle of patients causes a localized, temporary denervation and muscle paralysis. Such an effect is therapeutically useful for treating a number of conditions, including blepharospasm (an involuntary recurrent spasm of both eyelids) and for use in certain types of eye surgery. Studies on thousands of adults treated with Botox® have shown only mild side effects-e.g., a diffuse skin rash lasting several days-as a result of the localized muscle paralysis effects of the toxin. The only long-term effect reported is a slight reduction in the effectiveness of Botox® due to a person's natural immune responses.

**Aflatoxin.** Aflatoxin is a naturally occurring toxic metabolite from certain fungi that sometimes occur on grains, peanuts, and other foods stored under certain conditions.<sup>117</sup> Aflatoxin ingestion can result in immediate, toxic effects in many different species, and death results from acute liver toxicity.<sup>29,117</sup> Aflatoxicosis in humans has been reported following ingestion of aflatoxin contaminated food, and symptoms include vomiting, abdominal pain, pulmonary edema, gastrointestinal hemorrhage, convulsions, coma, and death.<sup>29</sup> Several epidemiologic studies suggest aflatoxin causes liver cancer in humans. The only documented health effect that could be expected from low-level exposure to aflatoxin would be an increased prevalence of liver cancer years to decades after exposure.

**What do we conclude about the risks of BW agents to Gulf War veterans?** In cases where an individual survives exposure to anthrax or botulinum toxin, no known, long-term health consequences exist. The Committee concludes it is unlikely the health effects reported today by Gulf War veterans are the result of exposures to BW agents. Aflatoxin, however, is a liver carcinogen, and increased rates of liver cancer could result decades following low-level exposure, although available evidence reviewed by the Committee does not indicate such exposures occurred during the Gulf War (see chapter 2).

### **Anthrax and Botulinum Toxoid Vaccines**

Before U.S. troops deployed to the Gulf region, they received a standard series of inoculations against infectious diseases-e.g., cholera, typhoid, tetanus, diphtheria, polio, and measles-that might be given to any U.S. citizen traveling to these regions. After arriving in the Gulf War region, some U.S. service members received two additional vaccines for protection against the BW agents anthrax and botulinum toxin.

**Anthrax vaccine.** In 1970, FDA licensed anthrax vaccine to protect civilian workers against possible infection by anthrax bacteria. Since 1967 and before the Gulf War, more than 20,000 inoculations had been routinely administered to at-risk populations, including laboratory personnel who work with the bacteria that causes anthrax, persons in industries that work with animal hides and wool (which can be a source of anthrax infection), and veterinarians who come in contact with anthrax-infected animals.

Although active long-term safety surveillance is not generally part of the FDA vaccine licensing process, the FDA encourages U.S. health care providers and the law requires manufacturers to report serious adverse reactions for all licensed vaccines.<sup>305</sup> FDA has not received data that raise concerns about the safety of the anthrax vaccine.

Historical data for short-term health effects of the anthrax vaccine indicate up to six percent of recipients experience mild discomfort, including tenderness, redness, swelling or itching at the inoculation site for up to 72 hours. Fewer than one percent experience a more severe local reaction that potentially limits the use of the arm for one to two days. Systemic reactions, e.g., fever, malaise, are uncommon (about 0.1

percent).<sup>102,103</sup>

According to DOD, medical monitoring and surveillance conducted during the Gulf War found the expected short-term side effects of anthrax vaccines occurring at approximately the historical rates.<sup>53</sup> A single hospitalization for a vaccination site infection was reported. DOD points out that precise information about all possible short-term side effects is unknown, however, because of difficulties in collecting such data during and after the Gulf War.

**Botulinum toxoid vaccine.** Botulinum toxoid (BT) vaccine has been used for more than 25 years to protect industry and laboratory workers from occupational exposure to the extremely poisonous botulinum toxins. All civilian vaccinations have been administered under an investigational new drug (IND) application sponsored by CDC. For both civilian and military use, BT vaccine remains in "investigational" status-i.e., not yet licensed by FDA.

Since 1970, as part of the IND evaluation, FDA has reviewed information from CDC about the cumulative safety record for BT vaccine. Records of more than 10,000 administered vaccine doses (including approximately 2,200 in the five years before the Gulf War) indicate that treated individuals experience only local side effects often associated with many types of vaccinations. These effects, primarily at the injection site, include local pain, tenderness, swelling, redness, and itching. Systemic reactions such as temporary fever, tiredness, headache, or muscle pain also can occur. Rarely, reactions include soreness of the arm sufficient to leave individuals unable to perform duties for a day or two or development of a lump at the injection site that generally resolves within several weeks. Such adverse reactions also are observed with other licensed toxoid vaccines, such as diphtheria and tetanus toxoids.<sup>53,102</sup>

The U.S. Army examined the frequency of side effects of BT vaccinations seen in some U.S. service members. In one report of 237 Gulf War veterans who had received BT vaccine, 2.5 percent had systemic reactions. This rate parallels that recorded by the U.S. Army and CDC prior to the Gulf War.<sup>127</sup>

**Precautions against contaminants.** The Committee examined the hypothesis that Gulf War veterans' illnesses could be the result of contamination of anthrax vaccine lots by *Mycoplasma incognitus*.<sup>182</sup> Discussions with staff of FDA, Walter Reed Army Medical Center, U.S. Army Medical Research and Materiel Command, academic experts, and the manufacturer of the vaccines indicate that *Mycoplasma* could not survive in the anthrax and BT vaccines.<sup>136,138,168,303</sup> *Mycoplasma* is difficult to grow, and the culture media used to produce Anthrax and BT vaccines do not contain serum, an essential ingredient for *Mycoplasma* growth. In addition, the vaccines are preserved and/or processed with other products that create a hostile environment for *Mycoplasma*, including:

- formaldehyde (anthrax and BT vaccines),
- benzethonium chloride (anthrax vaccine only),
- isotonic saline solution (BT vaccine only), and
- Thimerosal (BT vaccine only).

The Committee concludes it is unlikely that *Mycoplasma* organisms contaminated anthrax vaccine or BT vaccine.

**Health effects of multiple vaccines.** The human immune system has evolved the capability to deal with thousands of foreign substances, to sort them out, and to regulate immune response. Humans live among a vast population of hostile microorganisms, and vaccinations-even multiple, contemporaneous vaccinations-are a small part of total immune stimulation. Individual vaccines can cause adverse effects, but several studies of the effects of giving multiple vaccinations at one time have found no adverse effects associated with the practice. Research on this issue continues, but based on available evidence, the Committee believes it is unlikely that multiple vaccines are responsible for illnesses reported today by Gulf War veterans.<sup>202,219,268</sup>

**What do we conclude about the risks of vaccines to Gulf War veterans?** The Committee concludes it is unlikely that health effects reported by Gulf War veterans today are the result of exposures to the BT or anthrax vaccines, used alone or in combination.

### **Pyridostigmine Bromide**

PB is a pretreatment drug used to protect against the CW nerve agent soman. By itself PB is not protective against CW nerve agent poisoning. Used as a pretreatment, however, PB might enhance the antidote effects of the standard atropine and 2-PAM treatments used by the U.S. military for nerve agent poisoning.<sup>269</sup>

Since 1955, FDA has approved PB for use by persons suffering from myasthenia gravis. No long-term health problems thought to be associated with PB have been reported for persons with myasthenia gravis who regularly take PB over many years or decades.<sup>196,220</sup> DOD filed a New Drug Application in May 1996, but PB currently has the status of an IND for nerve gas pretreatment use.

According to FDA, its conclusion that PB was safe for use by U.S. service members during the Gulf War was based largely on the extensive cumulative experience with this drug in patients with myasthenia gravis. Typically these patients are treated with PB doses of up to 1,500 mg per day for many years, compared to the prescribed dose of 90 mg per day for a maximum of seven days use during the Gulf War. Reported side effects of PB include increased salivation, increased tearing, urinary urgency and frequency, nausea, vomiting, muscle weakness, abdominal cramps and diarrhea.<sup>167</sup> These effects disappear when individuals stop taking PB.

Data from one DOD retrospective study on 30 medical support officers of the 18th Airborne Corps reveal a similar range of short-term health effects from PB. The 18th Airborne Corps instructed 1,650 soldiers (6.5 percent women) to take PB tablets at the onset of Operation Desert Storm in January 1991. Half those surveyed reported gastrointestinal symptoms, 5 to 30 percent reported increased urinary urgency and frequency, and fewer than 5 percent reported headaches and tingling of extremities. The need for a medical visit was reported by less than 1 percent, and the decision to discontinue use based on medical advice was reported by less than 0.1 percent. As with myasthenia patients, DOD reported that side effects ceased when PB use was discontinued.<sup>110</sup> Other retrospective studies found similar results.<sup>32,270</sup>

A survey of 213 Israeli soldiers asked about possible symptoms of PB and their severity. The most frequent health complaints reported were generally mild and nonspecific, including dry mouth, general malaise, fatigue, and weakness, which appeared about 1.6 hours after taking the medication and recurred after each intake. For this group the typical side effects associated with PB, such as nausea, abdominal pain, frequent urination and runny nose, were infrequent.<sup>228</sup>

DOD recently completed a study begun in November 1994 that looked at differential tolerances to PB between women and men.<sup>128,296</sup> Ninety subjects, equally divided by gender and in three weight classes, took 30 mg of PB every 8 hours for 21 days (plus one dose). PB was found to be safe and well-tolerated. All side effects were mild and resolved with no intervention. Headaches, dizziness, nausea, rash, and hair loss were reported in both drug and placebo groups. Diarrhea and abdominal pain were reported in the PB group only (four study participants). Overall, the occurrence of adverse effects did not differ between active and placebo subjects, nor were differences observed among gender or weight groups. Results from a 1-year followup, indicated no long-term effects except possibly a skin rash that resolved with treatment.<sup>128</sup>

DOD continues to seek FDA approval to use PB for the protection of U.S. troops against CW agents. To support this approval process, DOD has sponsored various research efforts since 1984 to gather information on the effects of PB pretreatment on healthy individuals. To date, DOD reports no serious or long-term reactions from this research.

**Genetic predisposition to PB sensitivity.** Some scientists suggest that persons who are genetically unable to produce the plasma enzyme butyryl cholinesterase (BuChE) could be more sensitive to PB's known side effects, and at least one apparent case has been reported.<sup>139</sup> The estimated frequency in the general population of persons unable to produce BuChE is about 0.03 percent. Exposure to PB (or similar compounds) could cause immediate and marked health effects in these individuals. Based on studies of PB-related compounds in BuChE deficient individuals, however, symptoms vanish when exposure to PB is removed. Limited population genetic data indicate that about four percent of all people have slightly reduced ability to produce functional BuChE. It is unclear whether these individuals could be more susceptible to temporary PB side effects. 1,67,68,71,139,192,193,224,269

**Synergistic effects.** Concern has been raised about the possibility of increased health problems from PB when it is combined with other risk factors. Some researchers have hypothesized that PB in combination with stress may create central nervous system effects.<sup>59,170,228</sup> The insect repellent DEET and the insecticide permethrin are most often mentioned as cofactors with PB for Gulf War illnesses.

After the Gulf War, one U.S. Department of Agriculture researcher conducted a study on synergistic effects of various chemicals, including DEET and PB, on cockroaches. DEET showed a four-fold increase on the lethality of PB-i.e., it took one fourth as much PB to kill cockroaches in the presence of a sublethal dose of DEET.<sup>314</sup> In 1996, another researcher reported that PB given at near lethal levels to chickens could increase the toxicity of DEET and permethrin.<sup>1</sup> Under these conditions, nervous system damage to the chickens was reported. A 1995 DOD study with rats reported that PB caused a slight increase in lethality of DEET and permethrin when compared to expected additive values.<sup>263</sup>

These three studies report enhanced toxic effects from PB, DEET, and permethrin in combination. However, doses used in the laboratory experiments were far greater than exposures U.S. service members could have experienced during the Gulf War. Moreover, for DEET and permethrin, the routes of administration were not comparable to that used by U.S. service members in the Gulf War. For example, in the chicken model, DEET and permethrin were injected underneath the skin and, in the rat study, they were administered orally. During the war, DEET should have been applied to the skin, and permethrin should have been applied to the uniform.

These studies did not address the effect PB, DEET, and permethrin-individually or in combination-would have on morbidity in humans and what illnesses might be induced by such use. Neither did the studies answer whether there would have been detectable harmful effects in humans in-theater under the likely operational use by U.S. troops.

Some researchers suggest the immediate toxicity of the OP pesticides available to Gulf War veterans could have been increased from coexposure to PB,<sup>1,150,151</sup> leading to the well-characterized, long-term signs and symptoms of immediate and severe poisoning described earlier in this chapter. As previously mentioned, however, DOD reports that on-site medical personnel did not observe any immediate and severe effects of OP poisoning among U.S. service members, and the current scientific knowledge base indicates that long-term health effects do not occur in the absence of immediate poisoning.

In setting priorities for new research projects on Gulf War veterans' health issues, a subcommittee of the RWG of the Coordinating Board gave priority to toxicology studies on subtoxic exposures to PB and pesticides, either alone or in combination. Several federally funded studies now underway are assessing combined exposure to PB and other chemical risk factors.

**What do we conclude about the risks of PB to Gulf War veterans?** Given the extensive cumulative experience with the use of PB in patients with myasthenia gravis and data collected from military personnel, the Committee concludes it is unlikely that health effects reported today by Gulf War veterans are the result of exposure simply to PB. Ongoing federally funded studies should help the scientific community draw conclusions about the synergistic effects of PB and other risk factors.

## **Endemic Infectious Diseases**

During WWII, British military units were stationed in the Gulf region and based on this experience documented the nature of endemic infectious diseases. Thus, the U.S. command was concerned about diseases, including shigellosis, malaria, sandfly fever, and cutaneous leishmaniasis.<sup>6,65,90,187</sup> For example, cutaneous leishmaniasis, known locally as the Baghdad boil, is endemic to that area; 80 to 90 percent of people in some parts of Southwest Asia have scars from previous attacks.<sup>187</sup> During WWII, rates of sandfly fever were 3 to 10 percent of all troops in the Middle East, and in some units it exceeded 50 percent.<sup>187</sup> Infectious diseases during the Gulf War, however, were not a major cause of sickness or lost work time.<sup>90</sup> During the Gulf War, only one death due to infectious disease (meningococcal meningitis) was reported.<sup>342,343</sup>

Experts attribute the lack of a problem with infectious diseases during the Gulf War to a comprehensive infrastructure of medical care and preventive medicine efforts.<sup>90,185,271,273,293</sup> DOD took measures to minimize infectious disease risk, including strict monitoring of drinking water purity, inspecting food sources and supplies, maintaining field camp sanitation, and instituting an insect vector control program. U.S. service members received booster doses of routine vaccinations, including typhoid, meningococcus and, during the fall, influenza. Immune gamma globulin was used to prevent Hepatitis A, and the small number of troops who entered Iraq near the Euphrates River valley received drug prophylaxis for malaria.

Most of the combat troops were isolated in barren desert locations, distant from rivers, oases, and urban areas. Additionally, maximum troop deployment occurred during the cooler winter months, which provided the least favorable conditions for the transmission of insect-borne diseases.<sup>90,185</sup> Indeed, the majority of the 12 individuals who developed viscerotropic leishmaniasis had been deployed to urban areas.<sup>145</sup>

**Diagnosis of infectious diseases in-theater.** Short-term diarrhea was a common symptom among troops in-theater. Most cases were mild, traveler's-type diarrhea that resolved spontaneously without antibiotics after a few days.<sup>64,90</sup> Gastroenteritis among outpatients decreased from four percent per week early in the deployment to less than 0.5 percent per week after U.S. medical command tightened control of food sources-especially imposing a ban on locally-grown fresh fruits and vegetables. The most common organisms identified in service members with diarrhea severe enough to warrant cultures were *Shigella sonnei* and *Escherichia coli*. DOD reports no confirmed cases in-theater of food-borne, diarrheal diseases, such as cholera, typhoid fever, or giardiasis.<sup>90</sup>

DOD medical personnel evaluated U.S. service members for several diseases transmitted by insects, including leishmaniasis, sandfly fever, malaria, dengue, Sindbis, West Nile fever, Rift Valley fever, and Congo-Crimean hemorrhagic fever.<sup>90,293</sup> As noted, sandfly fever had been a major concern, but no cases were seen during the Gulf War. DOD reports detecting seven cases of malaria and one case of West Nile fever, a mosquito-borne viral illness. No rickettsial illnesses and no cases of other arthropod-borne viral illnesses were identified.

Viscerotropic leishmaniasis (VL) and cutaneous leishmaniasis (CL) are the only endemic infectious diseases demonstrated to cause chronic morbidity among a number of Gulf War service members. These diseases are transmitted through the bites of sand flies; person-to-person infection does not occur. Thirty-two cases of leishmaniasis were diagnosed among U.S. troops, consisting of 12 cases of VL and 20 cases of CL.<sup>145,277</sup> CL causes a characteristic ulcerative or nodular skin rash that can persist for more than a year without treatment. And, while VL can be difficult to confirm, it is not considered to be a cause of widespread illness in Gulf War veterans. All veterans diagnosed with VL, except one, have experienced the signs characteristic of the disease.<sup>90,146,293</sup>

It is unlikely that veterans in the Registry or CCEP who have unexplained illnesses are suffering from VL. The incidence of VL during the Gulf War and the five years since has been low (12 of 697,000), and other sandfly-borne infectious diseases in the troops have been absent.<sup>90,278</sup> Additionally, individuals



with unexplained illnesses also lack signs and symptoms characteristic of VL. VL can sometimes occur following a prolonged incubation period (more than 18 to 24 months); there is also a risk of activation of latent infections in immunosuppressed persons.<sup>65,90,146</sup> To date, DOD and VA report that delayed onset of VL has not occurred.

From August 1990 through July 1991, the U.S. Army deployed approximately 347,000 individuals to the Gulf region. Based on information from U.S. Army field hospitals, the only infectious diseases that caused 30 or more each of approximately 14,000 admissions were pneumonia, intestinal infections, inflammation of the testes and/or epididymus, chicken pox, and kidney infections.<sup>342,343</sup>

**What do we conclude about the risks of infectious diseases to Gulf War veterans?** Based on a review of the rates and types of the diseases diagnosed during and after the Gulf War, the Committee concludes it is unlikely that infectious diseases endemic to the Gulf region are responsible for long term health effects in Gulf War veterans, except in a small, known number of individuals.

### Depleted Uranium

Uranium is a naturally occurring, chemically toxic, and radioactive element composed of three isotopes. Relative to other radionuclides, natural uranium is only slightly radioactive because of its low specific activity.<sup>288</sup> When the uranium isotope used for nuclear reactors and weapons is extracted from natural uranium, DU is the byproduct.

DU is nearly twice as dense as lead—a property used to improve the performance of both armor and armor penetrating munitions. During the Gulf War, some U.S. tanks and U.S. aircraft fired DU munitions, which produced shrapnel and an aerosolized dust on impact with armor or on ignition in accidental munitions fires. DU retains natural uranium's toxicological properties and approximately half its radiological activity.<sup>267</sup> Most of DU's radiation cannot penetrate skin, and DU poses little threat to human health while it is external to the body.<sup>288</sup>

Because it is slightly radioactive, natural uranium is considered to be a potential carcinogen—albeit with a small cancer risk relative to other radionuclides.<sup>288</sup> Taken together, human and animal studies do not indicate conclusively that natural uranium causes cancer in humans. Epidemiologic studies of uranium miners experiencing extremely high, lifetime, occupational exposures to uranium show an increase in mortality due to lung cancer, but such cancers are thought to be caused by miners' concurrent exposures to radioactive radon gas and its decay products, tobacco smoke, silica and other dusts, or exhaust fumes from diesel engines.<sup>172,321</sup> Animal studies conclude that exposure to uranium for long periods of time does not result in increased incidence of cancer, except in the case of one study. This study found prolonged (more than five years) inhalation of high levels of uranium dioxide led to lung neoplasms in dogs.<sup>130,131</sup>

The chemical toxicity of uranium as a heavy metal is well characterized. In fact, the kidney is the most sensitive organ affected by exposure to uranium and is the critical target organ for risk assessment.<sup>133,218,322,341</sup> For this reason, uranium exposure is regulated based on its chemical toxicity and not its radiological properties.<sup>129,156</sup> Even so, more than 50 years of occupational health data from uranium miners reveal little epidemiologic evidence of excess kidney disease among workers exposed for years or decades.<sup>322</sup>

The health risks of internalized uranium or DU particles depend on dose, exposure pathway, and solubility of the ingested particle. Ingestion of insoluble uranium compounds poses little health hazard because they pass rapidly through the body and are eliminated in the feces. However, animal studies have shown that ingestion of large doses of relatively soluble uranium compounds are associated with kidney toxicity.<sup>129,288</sup> Inhaled uranium particles that are nonrespirable are cleared from the respiratory tract and either expelled from the body (cough) or swallowed and passed to the GI tract. Respirable and relatively soluble particles are cleared to blood and can affect kidney toxicity.<sup>14,129</sup> Less soluble particles can remain in the lung longer and in theory could pose a radiological hazard. The U.S. Army



has conducted tests to characterize aerosols associated with DU munitions impacts with armor and with accidental DU munitions fires; it concluded a service member's risk exceeds civilian safety standards only when he or she is inside a vehicle when it is penetrated by DU munitions.<sup>39,96,97</sup> The adequacy of the research supporting this conclusion has been questioned by some reviewers.<sup>229,267</sup>

No studies of long-term human health effects of uranium metal implanted in tissue exist. Nevertheless, toxic effects are likely to be similar to the kidney toxicity observed from inhaled or ingested uranium. To date, VA has reported no kidney toxicity among soldiers wounded by DU fragments in friendly fire episodes.<sup>112</sup> VA currently monitors the health of approximately 30 veterans suspected of retaining embedded DU fragments, and the U.S. Army Medical Research and Materiel Command is funding animals studies to investigate the health hazards associated with short- and long-term exposure to DU metal fragments.<sup>296</sup>

**What do we conclude about the risks of DU to Gulf War veterans?** The Committee concludes it is unlikely that health effects reported by Gulf War veterans today are the result of exposure to DU during the Gulf War. Since uranium is a potential carcinogen, it is possible that exposure to DU during the Gulf War could lead to a slight increase in the risk for lung cancer after decades following the end of the war.

### **Oil-well Fire Smoke**

At the end of the Gulf War, more than 600 Kuwaiti oil wells and several pools of spilled oil were left burning after being ignited by retreating Iraqi troops. Huge, dramatic plumes of billowing smoke from these fires rose high into the atmosphere. Occasionally the smoke remained low to the ground, in some cases enveloping U.S. military personnel.

Some chemicals contained in oil-well fire smoke, such as benzene and PAHs, are human carcinogens. As described earlier in this chapter, the amounts of these pollutants in the air were low. Hence, their contribution to excess cancer risk would be expected to be small and increased rates of cancers likely would not result. The U.S. Army used EPA's standardized methodology to estimate cancer and noncancer risks from the oil-well fire smoke.<sup>265</sup> It concluded "the potential for significant long-term adverse health effects for the exposed DOD troop or civilian employee populations is minimal." Risks from cancers were estimated not to exceed two excess cancers per one million people exposed, a value well within EPA's acceptable range.

Noncancer risks from smoke exposure were calculated as Hazard Indices (HI). When the HI exceeds 1.0, there can be concern about potential noncarcinogenic health effects. In Saudi Arabia, the HI ranged from 0.6 to 2.0, while in Kuwait it ranged from 2.0 to 5.0. Most of this noncancer risk was contributed by inhalation of VOCs, particularly benzene. The U.S. Army concluded that risk of noncarcinogenic health effects among the U.S. service members was low since HIs are based on EPA toxicity values that are set far below levels thought to cause health effects and that also account for sensitive subpopulations such as children and the elderly. A congressional Office of Technology Assessment analysis of the U.S. Army's risk assessment methods and findings concluded "the risks to health from exposure to the smoke and the background air contaminants in the Persian Gulf are likely to be extremely small."<sup>275</sup>

Oil-well fire smoke appears not to have caused observable changes in lung tissue. Researchers at the Armed Forces Institute of Pathology found no significant differences when they compared lung tissue from autopsies of 33 U.S. service members who died after the start of the oil well fires to lung tissue from autopsies of soldiers who died before the fires.<sup>164</sup>

Information has been gathered from 110 firefighters working for private companies in the Kuwaiti oil fields in 1991. Individuals were deployed for 28-day periods, working daily at the well heads without breathing-protection equipment. Most were over 30 years old and had 10 or more years experience fighting similar well fires, many of them in Kuwait and elsewhere in Southwest Asia. No cases of illnesses resembling those reported by Gulf War veterans were reported, nor have such complaints been observed among thousands of oil-well firefighters who have spent years experiencing similar

exposures.<sup>60,61</sup>

Known immediate health effects from inhaling large amounts of smoke and particulates are primarily respiratory, including coughing, wheezing, increased airway resistance, and respiratory infections. Toxic gases that can be found in oil-well fire smoke—such as hydrogen sulfide and sulfur dioxide—can cause eye and nose irritation, decreased pulmonary function, and increased airway reactivity.<sup>312,315</sup> Nevertheless, these toxic gases were not detected at high levels during the fires.<sup>89,289,302,339</sup> High levels of airborne particulates, which sometimes occurred in the Gulf region, are associated with increased rates of asthma and can exacerbate other chronic respiratory conditions. With chronic (months or years) exposure to particulates, there is increased risk of some loss in lung function or chronic bronchitis, especially in cigarette smokers.

**What do we conclude about the risks of oil-well fires to Gulf War veterans?** Based on research on human and animal health effects of exposure to air pollutants and on currently available exposure data, the Committee concludes it is unlikely exposure to oil-well fire smoke is responsible for symptoms reported today by Gulf War veterans. Although smoke from the oil-well fires did not include levels of carcinogens that would be expected to increase cancer rates among Gulf War participants, VA mortality studies will include cancer surveillance.

### Petroleum Products

Diesel, kerosene, gasoline, jet fuel, and other petroleum-based fuels were widely used during the Gulf War for dust suppression, waste incineration, and for fueling vehicles, stoves, heaters and generators. U.S. service members in certain jobs were occupationally exposed to petroleum fuel vapors and combustion products, such as toluene, xylene, benzene, ethyl benzene, carbon monoxide, sulfur dioxide, nitrogen dioxide, particulates, lead, and other pollutants. Additionally, in some areas near the Kuwaiti oil-well fires, unburned crude oil drizzled down, covering the ground and troops below.<sup>242</sup>

Petroleum fuels are a complex mixture of aliphatic hydrocarbons and aromatic hydrocarbons such as benzene and PAHs. These fuels also commonly contain various additives, like lead. When burned, petroleum fuels produce a variety of potentially hazardous combustion products. High-level, short-term exposures to fuel solvents can cause immediate effects. In most cases, however, complete recovery occurs when the exposure ceases.<sup>5,286</sup>

U.S. service members could have been exposed to petroleum fuels by inhalation, ingesting contaminated water or dust, and skin contact. Inhalation exposure could depress the central nervous system (CNS). Symptoms include short-term effects ranging from fatigue, headache, nausea, blurred vision, and dizziness, to convulsions, paralysis, and loss of consciousness depending on the dose.<sup>282,312</sup> Again, exposure to high, nonlethal levels usually is followed by complete recovery, although rare cases of permanent brain damage after massive exposure have been reported.<sup>117,205,282</sup>

Prolonged breathing of diesel fuel vapors can damage kidneys or lower blood clotting ability.<sup>284</sup> Studies of workers occupationally exposed to certain hydrocarbon solvents in petroleum fuels suggest that long-term high-dose exposure over 12 to 14 years can lead to neurotoxic effects.<sup>117,285</sup> For example, psychomotor disturbances, visual memory and perception, and visuomotor learning ability were significantly affected in exposed gasoline-pump workers compared to matched controls, particularly workers exposed for more than a year.<sup>125</sup> Some studies suggest there are neurotoxic effects from long-term exposure, including decrements in memory, cognitive functioning, and sometimes neuromotor functions.<sup>117</sup> Other researchers, however, have challenged the existence of what is sometimes referred to as "chronic toxic encephalopathy," and uncertainty exists about CNS effects from long-term, low-level exposures to solvents.<sup>69</sup>

Benzene makes up about one percent of U.S. gasoline and up to five percent of European formulations. It is a known human carcinogen that is associated with certain types of leukemia. Nevertheless, more than 55 published epidemiologic studies of workers exposed occupationally to hydrocarbons such as

gasoline generally do not replicate the carcinogenic effects reported for experimental animals.<sup>157,282</sup> Recent studies of refinery workers also do not reveal a clear association between gasoline production and leukemia.<sup>88,282</sup> Still, based on the limited evidence from animal studies and the presence of benzene in gasoline, the International Agency for Research on Cancer (IARC) concluded that gasoline is possibly carcinogenic to humans. It is not known if other petroleum products cause cancer in humans. IARC believes there are insufficient data to assess whether light fuel oils or light diesel fuels cause cancer in humans. However, IARC has determined that occupational exposure to fuel oils during petroleum refining is probably carcinogenic to humans.<sup>284</sup>

Although ingesting small amounts of fuel oils is unlikely to cause significant symptoms, ingesting fuel oils in larger quantities can cause vomiting, diarrhea, swelling of the stomach, stomach cramps, coughing, drowsiness, restlessness, irritability, and unconsciousness.<sup>284</sup> Ingestion of fuel oils can be accompanied (during vomiting) by aspiration of some of the material into the lungs, which can produce a chemical pneumonitis.

Skin exposure to large amounts of oil can physically clog pores and hair follicles, compromising body heat loss. Long-term exposure can cause acne and other skin problems. With high concentration or extended exposure, lighter components of crude oil or other fuel oils can defat the skin, leading to redness and itching or dermatitis.<sup>284,312</sup>

Exposure to the normal combustion products of petroleum fuels is also a health concern. Limited epidemiologic evidence indicates daily use of kerosene stoves for cooking or heating does not cause breathing problems for most people.<sup>284</sup> If insufficiently vented, however, carbon monoxide generated from fuel oil combustion can build up, causing drowsiness, nausea, and even asphyxiation. Individuals exposed to unvented combustion of fuels containing lead could experience health effects ranging from subtle biochemical changes in blood to severe CNS effects at high doses. Occupational exposure to inorganic lead is associated with subjective signs of neurotoxicity such as forgetfulness, lethargy, and weakness. These neurological signs and symptoms occur at about the same blood lead levels as other overt signs of lead intoxication, such as gastrointestinal complaints like abdominal pain, nausea, and vomiting.<sup>286</sup>

**What do we conclude about the risks of petroleum products to Gulf War veterans?** While certain subsets of Gulf War service members could have experienced occupational exposures to petroleum products that would entail increased risks of health effects, it is unlikely that health effects reported today by Gulf War veterans are due to exposure to petroleum products during the war.

### **Psychological and Physiological Stress**

Virtually all Gulf War participants were exposed to a wide range of stressors associated with the war. Throughout human history, observers have noted a correlation between the horrors of war and "mysterious" illnesses in soldiers and veterans.<sup>91</sup> Only recently, however, have the broad range of symptoms for such illnesses been recognized as serious, physiological effects of stress.

Unexplained illnesses in soldiers were widely interpreted as a form of malingering until the 1940s. When WWII veterans experienced many of the same symptoms seen in WWI, Charles Samuel Dyers coined the term "shell shock." He began to study and write about what actually happened to the minds and bodies of soldiers on and off the battlefield. Physicians began to describe psychosomatic symptoms-physical disorders caused or influenced by a psychological state-as the normal and expected consequences of experiencing fear and fright, and recognized the relationship between intense emotion and bodily changes.

During this period, a telling example came to light that illustrated how traumatic experience can lead to a decline in physical health. A group of merchant marines in Norway during WWII were preselected for their excellent physical and mental health. Yet after exposure to extraordinary stress, they showed a sharp decline in their health. Many had symptoms of chronic fatigue, chronic pain, impotence, and

irritability.

Today, scientists are beginning to unravel the physiological connection between the brain and various other parts of the human body. Recent animal and human studies reveal numerous pathways connecting the brain to the rest of the body, through which psychological stress can be physically expressed.<sup>31</sup> Animal studies demonstrate that stress can have measurable effects on the brain, immune system, cardiovascular system, and various hormonal responses. Although the human body can adapt to normal stresses, if the stress lasts longer it can be expressed in a variety of physical illness symptoms.<sup>155</sup> Some researchers suspect that the inadequate production of stress hormones and stress response occurs in some (not all) humans with CFS and PTSD.<sup>31</sup>

Based on this understanding and supported by decades of clinical observations, physicians recognize that many physical, as well as psychological, diagnoses are the consequences of stress. This connection is not limited to soldiers only. Experts now know that conventional stressors, such as bereavement, family problems, financial and job problems, domestic or other violence, can cause significant and long-term physical health effects.<sup>76,184</sup>

Physicians and scientists also note substantial variability in the human response to stress. One individual's reaction to trauma could be hypertension; in another individual, the reaction to similar trauma might be severe anxiety. A number of medical diagnoses are linked with stress, including somatoform disorders, CFS and FM. These conditions share many overlapping features, and each diagnosis depends on meeting specific case definitions. Significant evidence supports the likelihood of a physiological, stress-related origin for many of these ailments.

**What do we conclude about the risks of stress to Gulf War veterans?** The Committee concludes that stress does not cause a unique illness or set of symptoms. Stress can contribute to a broad range of physiological and psychological illnesses. Stress is likely to be an important contributing factor to the broad range of illnesses currently being reported by Gulf War veterans.

## SUMMARY

The Committee has examined exposure and, independently, expected health effects for ten Gulf War risk factors: pesticides, CW agents, BW agents, vaccines, PB, infectious disease, DU, oil-well fire smoke, petroleum products, and psychological and physiological stress. In our evaluation, we used the substantial amount of relevant scientific information available in published peer reviewed literature, interviews with experts, invited testimony, public comment, and discussions with scientific experts in academic and government agencies. For most of the risk factors evaluated, the Committee has determined-even in the absence of exposure data-they are unlikely to be associated with the health problems currently reported by Gulf War veterans. Based on its review, the Committee makes the following findings and recommendations.

## FINDINGS

- Although some veterans clearly have service-connected illnesses, current scientific evidence does not support a causal link between the symptoms and illnesses reported today by Gulf War veterans and exposures while in the Gulf region to the following environmental risk factors assessed by the Committee: pesticides, chemical warfare agents, biological warfare agents, vaccines, pyridostigmine bromide, infectious diseases, depleted uranium, oil-well fires and smoke, and petroleum products. Some of these risk factors explain specific, diagnosed illness in a few Gulf War veterans, for example, leishmaniasis has been diagnosed in 32 individuals. Prudence requires further investigation of some areas of uncertainty, such as the long-term effects of low-level exposure to chemical warfare agents and the synergistic effects of exposure to pyridostigmine bromide and other risk factors.
- A number of Gulf War risk factors-e.g., mustard agent, aflatoxin, and certain petroleum products-are potential human carcinogens that could cause increased rates of cancer beginning decades after exposure.

- Stress is known to affect the brain, immune system, cardiovascular system, and various hormonal responses. Stress manifests in diverse ways, and is likely to be an important contributing factor to the broad range of physiological and psychological illnesses currently being reported by Gulf War veterans.

## RECOMMENDATIONS

- DOD and VA should perform long-term mortality studies of Gulf War veterans appropriate for investigating cancer rates in the Gulf War veteran population in the coming decades.
- The entire federal research portfolio should place greater emphasis on basic and applied research on the physiologic effects of stress and stress-related disorders.

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\*As noted, individuals in this group also were assessed for SCEs, which were found to increase with deployment to Kuwait and remain elevated even after the return to Germany.<sup>154</sup> SCEs are a sensitive measure of DNA damage and repair and occur at a background rate in normal cells, but increase with exposures to DNA damaging agents. It is not clear what exposures in Kuwait could have led to the observed increases, since elevated SCEs are a nonspecific measure that can reflect exposure to infections and vaccinations, or to dietary, occupational, or environmental mutagens.

\*\*In chapter 2, we identify those areas for which we believe new research data could fill in current gaps in knowledge.

THE WHITE HOUSE  
Office of the Press Secretary

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For Immediate Release May 26, 1995

EXECUTIVE ORDER

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PRESIDENTIAL ADVISORY COMMITTEE ON GULF  
WAR VETERANS' ILLNESSES

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

**Section 1. Establishment.** (a) There is hereby established the Presidential Advisory Committee on Gulf War Veterans' Illnesses (the "Committee"). The Committee shall be composed of not more than 12 members to be appointed by the President. The members of the Committee shall have expertise relevant to the functions of the Committee and shall not be full-time officials or employees of the executive branch of the Federal Government. The Committee shall be subject to the Federal Advisory Committee Act, as amended, 5 U. S. C. App. 2.

(b) The President shall designate a Chairperson from among the members of the Committee.

**Sec. 2. Functions.** (a) The Committee shall report to the President through the Secretary of Defense, the Secretary of Veterans Affairs, and the Secretary of Health and Human Services.

(b) The Committee shall provide advice and recommendations based on its review of the following matters:

(1) **Research:** epidemiological, clinical, and other research concerning Gulf War veterans' illnesses.

(2) **Coordinating Efforts:** the activities of the Persian Gulf Veterans Coordinating Board, including the Research Coordinating Council, the Clinical Working Group, and the Disability and Compensation Working Group.

(3) **Medical Treatment:** medical examinations and treatment in connection with Gulf War veterans' illnesses, including the Comprehensive Clinical Evaluation Program and the Persian Gulf Registry Medical Examination Program.

(4) **Outreach:** government-sponsored outreach efforts such as hotlines and newsletters related to Gulf War veterans' illnesses.

(5) **External Reviews:** the steps taken to implement recommendations in external reviews by the Institute of Medicine's Committee to Review the Health Consequences of Service During the Persian Gulf War, the Defense Science Board Task Force on Persian Gulf War Health Effects, the National Institutes of Health Technology Assessment Workshop on the Persian Gulf Experience and Health, the Persian Gulf Expert Scientific Committee, and other bodies.

more

(6) **Risk Factors:** the possible risks associated with service in the Persian Gulf Conflict in general and, specifically, with prophylactic drugs and vaccines, infectious diseases, environmental

chemicals, radiation and toxic substances, smoke from oil well fires, depleted uranium, physical and psychological stress, and other factors applicable to the Persian Gulf Conflict.

(7) **Chemical and Biological Weapons:** information related to reports of the possible detection of chemical or biological weapons during the Persian Gulf Conflict.

(c) It shall not be a function of the Committee to conduct scientific research. The Committee shall review information and provide advice and recommendations on the activities undertaken related to the matters described in (b) above.

(d) It shall not be a function of the Committee to provide advice or recommendations on any legal liability of the Federal Government for any claims or potential claims against the Federal Government.

(e) As used herein, "Gulf War Veterans' Illnesses" means the symptoms and illnesses reported by United States uniformed services personnel who served in the Persian Gulf Conflict.

(f) The Committee shall submit an interim report within 6 months of the first meeting of the Committee and a final report by December 31, 1996, unless otherwise provided by the President.

**Sec. 3. Administration.** (a) The heads of executive departments and agencies shall, to the extent permitted by law, provide the Committee with such information as it may require for purposes of carrying out its functions.

(b) Members of the Committee shall be compensated in accordance with Federal law. Committee members may be allowed travel expenses, including per diem in lieu of subsistence, to the extent permitted by law for persons serving intermittently in the Government service (5 U.S.C. 5701-5707).

(c) To the extent permitted by law, and subject to the availability of appropriations, the Department of Defense shall provide the Committee with such funds as may be necessary for the performance of its functions.

**Sec. 4. General Provisions.** (a) Notwithstanding the provisions of any other Executive order, the functions of the President under the Federal Advisory Committee Act that are applicable to the Committee, except that of reporting annually to the Congress, shall be performed by the Secretary of Defense, in accordance with the guidelines and procedures established by the Administrator of General Services.

(b) The Committee shall terminate 30 day after submitting its final report.

(c) This order is intended only to improve the internal management of the executive branch and it is not intended to create any right, benefit or trust responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, its officers, or any person.

WILLIAM J. CLINTON

THE WHITE HOUSE

May 26, 1995

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## **Presidential Advisory Committee on Gulf War Veterans' Illnesses Final Report**

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## **Final Report w**

## **w Presidential Advisory Committee**

**Presidential Advisory Committee  
Final Report**

# Appendix A

## Executive Order 12961

**THE WHITE HOUSE**

**Office of the Press Secretary**

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**For Immediate Release. May 26, 1995**

**EXECUTIVE ORDER**

**PRESIDENTIAL ADVISORY COMMITTEE ON GULF  
WAR VETERANS' ILLNESSES**

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

**Section 1. Establishment.** (a) There is hereby established the Presidential Advisory Committee on Gulf War Veterans' Illnesses (the "Committee"). The Committee shall be composed of not more than 12 members to be appointed by the President. The members of the Committee shall have expertise relevant to the functions of the Committee and shall not be full-time officials or employees of the executive branch of the Federal Government. The Committee shall be subject to the Federal Advisory Committee Act, as amended, 5 U. S. C. App. 2.

(b) The President shall designate a Chairperson from among the members of the Committee.

**Sec. 2. Functions.** (a) The Committee shall report to the President through the Secretary of Defense, the Secretary of Veterans Affairs, and the Secretary of Health and Human Services.

(b) The Committee shall provide advice and recommendations based on its review of the following matters:

(1) **Research:** epidemiological, clinical, and other research concerning Gulf War veterans' illnesses.

(2) **Coordinating Efforts:** the activities of the Persian Gulf Veterans Coordinating Board, including the Research Coordinating Council, the Clinical Working Group, and the Disability and Compensation Working Group.

(3) **Medical Treatment:** medical examinations and treatment in connection with Gulf War veterans' illnesses, including the Comprehensive Clinical Evaluation Program and the Persian Gulf Registry Medical Examination Program.

(4) **Outreach:** government-sponsored outreach efforts such as hotlines and newsletters related to Gulf War veterans' illnesses.

(5) **External Reviews:** the steps taken to implement recommendations in external reviews by the Institute of Medicine's Committee to Review the Health Consequences of Service During the Persian Gulf War, the Defense Science Board Task Force on Persian Gulf War Health Effects, the National

Institutes of Health Technology Assessment Workshop on the Persian Gulf Experience and Health, the Persian Gulf Expert Scientific Committee, and other bodies.

(6) **Risk Factors:** the possible risks associated with service in the Persian Gulf Conflict in general and, specifically, with prophylactic drugs and vaccines, infectious diseases, environmental chemicals, radiation and toxic substances, smoke from oil well fires, depleted uranium, physical and psychological stress, and other factors applicable to the Persian Gulf Conflict.

(7) **Chemical and Biological Weapons:** information related to reports of the possible detection of chemical or biological weapons during the Persian Gulf Conflict.

(c) It shall not be a function of the Committee to conduct scientific research. The Committee shall review information and provide advice and recommendations on the activities undertaken related to the matters described in (b) above.

(d) It shall not be a function of the Committee to provide advice or recommendations on any legal liability of the Federal Government for any claims or potential claims against the Federal Government.

(e) As used herein, "Gulf War Veterans' Illnesses" means the symptoms and illnesses reported by United States uniformed services personnel who served in the Persian Gulf Conflict.

(f) The Committee shall submit an interim report within 6 months of the first meeting of the Committee and a final report by December 31, 1996, unless otherwise provided by the President.

**Sec. 3. Administration.** (a) The heads of executive departments and agencies shall, to the extent permitted by law, provide the Committee with such information as it may require for purposes of carrying out its functions.

(b) Members of the Committee shall be compensated in accordance with Federal law. Committee members may be allowed travel expenses, including per diem in lieu of subsistence, to the extent permitted by law for persons serving intermittently in the Government service (5 U.S.C. 5701-5707).

(c) To the extent permitted by law, and subject to the availability of appropriations, the Department of Defense shall provide the Committee with such funds as may be necessary for the performance of its functions.

**Sec. 4. General Provisions.** (a) Notwithstanding the provisions of any other Executive order, the functions of the President under the Federal Advisory Committee Act that are applicable to the Committee, except that of reporting annually to the Congress, shall be performed by the Secretary of Defense, in accordance with the guidelines and procedures established by the Administrator of General Services.

(b) The Committee shall terminate 30 day after submitting its final report.

(c) This order is intended only to improve the internal management of the executive branch and it is not intended to create any right, benefit or trust responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, its officers, or any person.

WILLIAM J. CLINTON

THE WHITE HOUSE  
May 26, 1995.

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Appendix B: Advisory Committee Charter

**Presidential Advisory Committee  
Final Report**

## **Appendix B**

### **CHARTER OF THE PRESIDENTIAL ADVISORY COMMITTEE ON GULF WAR VETERANS' ILLNESSES**

**A. COMMITTEE'S OFFICIAL DESIGNATION:** Presidential Advisory Committee on Gulf War Veterans' Illnesses ("Committee").

**B. AUTHORITY:**

Executive Order No. 12961

**C. OBJECTIVES, SCOPE OF ACTIVITIES, AND DESCRIPTION OF DUTIES FOR WHICH THE COMMITTEE IS RESPONSIBLE:** The duties of the Committee are solely advisory. The Committee shall provide to the President, through the Secretary of Defense, the Secretary of Health and Human Services, and the Secretary of Veterans Affairs, advice and recommendations based on its review of the following matters:

- 1. *Research:* epidemiological, clinical and other research concerning Gulf War veterans' illnesses.
- 2. *Coordinating efforts:* the activities of the Persian Gulf Veterans Coordinating Board, including the Research Coordinating Council, the Clinical Wording Group, and the Disability and Compensation Working Group.
- 3. *Medical treatment:* medical examinations and treatment in connection with Gulf War veterans' illnesses, including the Comprehensive Clinical Evaluation Program and the Persian Gulf Registry Medical Examination Program.
- 4. *Outreach:* government-sponsored outreach efforts such as hotlines and newsletters relating to Gulf War veterans' illnesses.
- 5. *External reviews:* the steps taken to implement recommendation in external reviews by the Institute of Medicine's Committee to Review the Health Consequences of Service During the Persian Gulf War, the Defense Science Board Task Force on Persian Gulf War Health Efforts, the National Institutes of Health Technology Assessment Workshop on the Persian Gulf Experience and Health, the Persian Gulf Expert Scientific Committee, and other bodies.
- 6. *Risk factors:* the possible risks associated with service in the Persian Gulf Conflict in general and, specifically, with prophylactic drugs and vaccines, infectious diseases, environmental chemicals, radiation and toxic substances, smoke from oil well fires, depleted uranium, physical and psychological stress, and other factors applicable to the Persian Gulf Conflict.
- 7. *Chemical and Biological Weapons:* information related to reports of the possible detection of chemical or biological weapons during the Persian Gulf Conflict.

It shall not be a function of the Committee to conduct independent scientific research. The Committee shall review information and provide advice and recommendations on the activities undertaken related to the matters described above. It shall not be a function of the Committee to provide advice or recommendations on any legal liability of the Federal Government for any claims or potential claims against the Federal Government. As used herein, "Gulf War Veterans' Illnesses" means the symptoms and illnesses reported by United States uniformed services personnel who served in the Persian Gulf conflict.

**D. OFFICIAL TO WHOM THE COMMITTEE REPORTS:** The Committee shall report to the President through the Secretary of Defense, Secretary of Health and Human Services, and Secretary of Veterans Affairs. The Committee shall submit an interim report within six months of the first meeting of

the Committee and a final report by December 31, 1996, unless otherwise provided by the President.

**E. DURATION AND TERMINATION DATE:** The Committee shall terminate thirty days after submitting its final report.

**F. AGENCY RESPONSIBLE FOR PROVIDE NECESSARY SUPPORT:** Financial and administrative support shall be provided by the Department of Defense.

**G. MEMBERSHIP:** The President shall appoint up to a maximum of twelve (12) members. Committee members shall have expertise relevant to the functions of the Committee and shall not be full-time officials or employees of the executive branch of the Federal Government. Committee members shall be compensated in accordance with federal law. Committee members may be allowed travel expenses, including per diem in lieu of subsistence, to the extent permitted by law for persons serving intermittently in the government service (5 U.S.C. 5701-5707).

**H. ESTIMATED ANNUAL OPERATING COSTS AND STAFF SUPPORT YEARS:** It is estimated that the total annual costs of operations will not exceed \$3.5 million. Full time equivalent staff support years are expected to be approximately 30 years of effort.

**I. NUMBER OF MEETINGS:** The Committee shall meet as it deems necessary to complete its functions.

**J. SUBCOMMITTEE(S) :** To facilitate functioning of the Committee, subcommittee (s) may be formed. The objectives of the subcommittee(s) are to provide advice and recommendations to the Committee with respect to matters related to the duties of the Committee. Subcommittees shall meet as the Committee deems appropriate.

**K. CHAIRPERSON:** The President shall designate a chairperson from among the members of the Committee.

**L. DATE OF CHARTER FILED:** JULY 3, 1995.

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[Appendix C: Staff and Consultants](#)



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## Presidential Advisory Committee on Gulf War Veterans' Illnesses

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### **Joyce C. Lashof, M.D., *Committee Chair***

is former Dean and Professor Emerita of the School of Public Health at the University of California at Berkeley. Dr. Lashof was Assistant Director of the Office of Technology Assessment from 1978-81 and Deputy Assistant Secretary for Health Programs and Deputy Assistant Secretary for Population Affairs at the Department of Health, Education, and Welfare from 1977-78. She served as President of the American Public Health Association in 1991-92.

### **John Baldeschwieler, Ph.D.**

is Professor of Chemistry and former Chair of the Division of Chemistry and Chemical Engineering at the California Institute of Technology. From 1971-73, Dr. Baldeschwieler served as Deputy Director of the White House Office of Science and Technology Policy. He is an expert on national security issues, having served on numerous scholarly panels, commissions, and committees.

### **Arthur Caplan, Ph.D.**

is Director of the Center for Bioethics at the University of Pennsylvania. Dr. Caplan was Director of the Center for Biomedical Ethics and Professor of Philosophy and Professor of Surgery at the University of Minnesota from 1987-94. He is an authority on ethics and medicine, and serves as the first President of the American Association of Bioethics.

### **Thomas P. Cross**

is currently a Major in the United States Marine Corps Reserve who was activated during Operation Desert Shield/Desert Storm. He was an Assistant Operations Officer for the 6th Marine Regiment in the Gulf, where he participated in the initial attack across the Kuwaiti border in February 1991. He is the recipient of the Navy Commendation Medal with Combat 'V', as well as the Combat Action Ribbon and the Kuwait Liberation Medal. Mr. Cross earned a B.S. in marketing from Central Connecticut State University and is continuing his education toward a Certification in Purchasing Management (CPM). He is currently a sales representative for Bell Industries, an electronics components distributor in Meriden, Connecticut.

### **Donald Custis, M.D.**

is the Senior Medical Advisor to the Health Policy Department of the Paralyzed Veterans of America. From 1980-84, he served as Chief Medical Director for the Veterans Administration, having joined VA in 1976. During his career, he served as Commanding Officer of the Naval Combat Hospital in Danang, Vietnam (1969), followed by command of the National Naval Medical Center in Bethesda, Maryland. He retired in 1976 as the U.S. Navy Surgeon General, with the rank of Vice Admiral.

### **David A. Hamburg, M.D.**

is President of the Carnegie Corporation. Dr. Hamburg was President of the Institute of Medicine, National Academy of Sciences from 1975-80, and Director of the Division of Health Policy Research and Education and John D. MacArthur Professor of Health Policy at Harvard University from 1980-82. He served as President, then Chairman of the Board, of the American Association for the Advancement of Science, between 1984-86.

### **James A. Johnson**

is Chairman and Chief Executive Officer of the Federal National Mortgage Association in Washington, DC. Mr. Johnson was a managing director at Lehman Brothers from 1985-90, and Executive Assistant to

Vice President Walter Mondale from 1977-81. He is Chairman of the Board of Trustees of the Brookings Institution and also serves on the Boards of the Carnegie Endowment for International Peace and the Carnegie Corporation.

**Marguerite Knox, M.N., R.N.C., C.C.R.N.**

is a Clinical Assistant Professor at the College of Nursing of the University of South Carolina in Columbia, and a Major in the South Carolina Army National Guard. As a member of the U.S. Army Nurse Corps, Major Knox was stationed with the 251st evacuation hospital at King Khalid Military City during Operation Desert Shield and Desert Storm. From 1988-93, she was a Special Nurse, Peripheral Vascular Lab at the William Jennings Bryan Dorn Veterans Hospital in Columbia, South Carolina.

**Philip J. Landrigan, M.D.**

is Director of the Division of Environmental and Occupational Medicine at the Mount Sinai School of Medicine in New York and a Lieutenant Commander in the United States Naval Reserve. Dr. Landrigan is an expert on toxic environmental and occupational exposures, and is Editor-in-Chief of the *American Journal of Industrial Medicine* and former Editor-in-Chief of *Environmental Research*. In 1988, he served as Chair of the science committee that reviewed the health effects of Agent Orange for the American Legion. Dr. Landrigan served as an epidemiologist with the Centers for Disease Control and Prevention from 1970-1985.

**Elaine L. Larson, Ph.D., R.N., F.A.A.N., C.T.C.**

is Dean of the Georgetown University School of Nursing. Dr. Larson was Professor and Nutting Chair in Clinical Nursing at the Johns Hopkins University School of Nursing and Director of the School's Center for Nursing Research from 1985-92. She is a member of the Health Sciences Policy Board of the Institute of Medicine, National Academy of Sciences, and is a Trustee of the Research Foundation of the Association of Practitioners in Infection Control. She has been a consultant in infection prevention in the U.S., Kuwait, Singapore, South America, Australia, Ghana, and Europe.

**Rolando Rios**

is a public interest attorney in private practice in San Antonio, Texas. From 1969-72, Mr. Rios served in the U.S. Army. He earned the rank of First Lieutenant and was disabled while serving at Cam Ranh Bay during the Vietnam War.

**Andrea Kidd Taylor, Dr.P.H.**

is an industrial hygienist and occupational health policy consultant for the International Union, United Automobile, Aerospace and Agricultural Implement Workers of America (UAW) in Detroit, Michigan. Dr. Taylor is a health representative on the National Advisory Committee for Occupational Safety and Health. From 1984-89, she was an industrial hygiene consultant for the Maryland Committee on Occupational Safety and Health.

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**Presidential Advisory Committee on Gulf War Veterans' Illnesses  
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**APPENDIX D - ADVISORY COMMITTEE STAFF AND CONSULTANTS**

***Executive Director***

Robyn Y. Nishimi, Ph.D.

***Deputy Director/Counsel***

Holly L. Gwin, Esq.

***Director of Public Affairs***

Gary Caruso

***Research Staff***

Joseph S. Cassells, M.D., M.P.H. - Senior Advisor for Medical and Clinical Affairs

Kathi E. Hanna, M.S., Ph.D. - Senior Advisor for Policy and Reproductive Health

Kelley A. Brix, M.D., M.P.H. - Senior Policy Analyst

Mark A. Brown, Ph.D. - Senior Policy Analyst

Miles W. Ewing - Special Assistant and Coordinator, Public Affairs<sup>1</sup>

Lois M. Joellenbeck, Dr.P.H. - Senior Policy Analyst

Michael E. Kowalok, M.A. - Policy Analyst and Coordinator, Subcommittee Affairs

John D. Longbrake - Research Analyst and Coordinator, Public Affairs

Thomas C. McDaniels, Jr. - Policy Analyst

Joan P. Porter, M.P.H., D.P.A. - Senior Policy Analyst

Nicole M. Stern - Research Analyst

James C. Turner, Esq. - Senior Policy Analyst

***Administrative Staff***

Carol A. Bock, Executive Assistant

Barbara A. Bradley - Conference and Travel Services/Technical Editor

Michael R. Brown - Administrative Services

Philip B. Jackson - Telecommunications and Computing Services<sup>2</sup>

Barbara V. Ketchum - Administrative Secretary

Vincent E. McCall, Jr. - Telecommunications and Computing Services

Debra J. McCurry - Information and Reference Services

M. Cecile Parker - Administrative Officer

Linda S. Rayford - Desktop Publishing/Word Processing Specialist

Tracy C. Smith - Administrative Secretary

***Other Contributors***

Mary Lou Higgs

Susan J. Hoffmeyer

Timothy E. Phillips, Esq.

Jonathan B. Tucker, Ph.D.

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<sup>1</sup> Through August 1996

<sup>2</sup> Through April 1996

**Presidential Advisory Committee on Gulf War Veterans' Illnesses  
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**APPENDIX E - ADVISORY COMMITTEE MEETINGS**

**FULL COMMITTEE MEETINGS**

August 14-15, 1995  
Washington, DC

October 18-19, 1995  
Arlington, VA

December 4-5, 1995  
San Diego, CA

January 31, 1996  
Washington, DC

March 26, 1996  
Boston, MA

May 1-2, 1996  
Washington, DC

July 7-8, 1996  
Chicago, IL

September 4-5, 1996  
Washington, DC

October 9, 1996  
Tampa, FL

November 13, 1996  
Washington, DC

**PANEL MEETINGS**

*Clinical Issues*  
September 18, 1995  
Charlotte, NC

*Epidemiologic Research*  
November 7-8, 1995  
San Francisco, CA

*Use of Investigational Drugs and Vaccines*  
January 12, 1996  
Kansas City, MO

*Clinical Syndromes*  
February 27, 1996  
San Antonio, TX

*Possible Exposures to Chemical or Biological Warfare Agents*  
April 16, 1996

Atlanta, GA

*Reproductive Health*

June 17-18, 1996

Seattle, WA

*Biology and Psychology of Stress*

July 23, 1996

Cincinnati, OH

*Persian Gulf Veterans' Illnesses Investigation Team and Risk Factors*

August 4, 1996

Denver, CO

## Appendix F - Federally Funded Research on Gulf War Veterans' Health Through Fiscal Year 1996

### GROUP I: Exploratory and Epidemiologic Research on Health, Rates of Diseases and Death, and Possible Association with Risk Factors

Study title, focus highlighted	Facility <sup>a</sup>	Funding agency	Estimated completion	Referenc
<b>Health and Exposure Survey of Persian Gulf Veterans</b> (general health symptoms, CFS, MCS, exposures)	VAMC East Orange	VA	Complete	Manuscri in preparat
<b>Gulf War and Vietnam Veterans Cancer Incidence Surveillance</b>	VAMC Boston	VA	9/99	None
<b>A Controlled Epidemiological and Clinical Study into the Effect of Gulf War Service on Servicemen and Women of the United Kingdom Armed Forces</b> (general health symptoms, CFS, psychiatric conditions, neuropsychological outcomes, respiratory function)	King's College School of Medicine, UK	DOD	6/99	None
<b>Epidemiological Studies of Persian Gulf War Illnesses, Persian Gulf Women's Health Linkage Study</b> (general health symptoms, reproductive outcomes, cancer, psychological conditions)	Klemm Analysis Group, Inc., Washington, DC	DOD	1/99	None
<b>Risk Factors Among U.S. Army Soldiers for Enrolling in the Department of Veterans Affairs Gulf War Registry</b> (demographics, aptitude test scores, hospitalizations, self-reported health behaviors)	WRAIR	DOD and VA	Complete	Manuscri in preparat
<b>Epidemiological Study of Gulf War Veteran Registrants</b> (risk factors associated with enrollment in CCEP or VA Registry)	NHRC	DOD	5/97	None
<b>The General Well-being of Gulf War Era Service Personnel from the States of Pennsylvania and Hawaii: A Survey</b> (general symptoms, PTSD, and other psychological conditions)	WRAIR	DOD	Complete	245-247, 272,340
<b>Epidemiologic Studies of Morbidity among Gulf War Veterans: A Search for Etiologic Agents and Risk Factors-Study 6: A Comparison of Nonfederal Hospitalization Experience among Veterans in California Who Have Separated from Active Service, Persian Gulf War v. Era Veterans</b>	NHRC	DOD	6/97	None
<b>Epidemiologic Studies of Morbidity</b>	NHRC	DOD	Survey in	None

among Gulf War Veterans: A Search  
for Etiologic Agents and Risk  
Factors-Study 5: Seabee mail survey  
(chronic disease outcomes)

OMB review

Epidemiologic Studies of Morbidity  
among Gulf War Veterans: A Search  
for Etiologic Agents and Risk  
Factors-Study 2: A Comparative  
Study of **Hospitalizations** Among  
Active Duty Personnel Who  
Participated in the Gulf War and  
Similar Personnel Who Did Not

NHRC

DOD

Complete

33,75

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**GROUP I (cont.):**


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**Disease Cluster** in a Pennsylvania  
Air National Guard Unit (general  
health symptoms, psychiatric  
outcomes, infectious diseases)

CDC and  
Pennsylvania  
Department of  
Health

DHHS

Phases 1,2  
complete;  
phase 3  
analysis  
ongoing

291

**Health Assessment** of Persian Gulf  
Veterans from Iowa (CFS, FM,  
psychological conditions, cognitive  
dysfunction, reproductive outcomes)

CDC and Iowa  
Department of  
Public Health

DHHS

1/97

Manuscri  
submitte

CORE [Clinical and Epidemiology  
Research] Project, Portland  
Environmental Hazards Research  
Center: **Environment, Veterans  
Health, and the Gulf War Syndrome**  
(general health symptoms and  
diseases, reproductive outcomes,  
stress, psychological conditions)

VAMC Portland

VA

9/99

None

Epidemiologic Studies of Morbidity  
Among Gulf War Veterans: A Search  
for Etiologic Agents and Risk  
Factors-Study 1: A Study of  
**Symptoms among 1,500 Seabees**  
(general health symptoms, hand grip  
strength, respiratory function)

NHRC

DOD

Complete

106

**National Health Survey** of Persian  
Gulf Veterans (survey of general  
health status, examining general  
health symptoms and diseases,  
reproductive outcomes, stress,  
psychological conditions)

EES

VA

Phase 1  
complete;  
phase 2  
ongoing,  
5/98

None

**Mortality Follow-up Study** of Persian  
Gulf Veterans

EES

VA

Complete;  
long-term  
followup  
ongoing

108

United States **Military Casualty**  
Comparisons During the Persian Gulf

National  
Institute for

DHHS

Complete

85

War	Occupational Safety and Health			
<i>Comparative Mortality Among U.S. Military Personnel Worldwide During Operations Desert Shield/Storm</i>	WRAIR	DOD	Complete	343
<i>Health and Psychosocial Readjustment of Gulf War Veteran Women</i>	University of Michigan	DOD	Complete	199-201
<i>Health of Persian Gulf War Veteran Women</i>	University of Michigan	DOD	8/99	None
<i>Exploratory Data Analysis with the CCEP Database</i>	Naval Postgraduate School, MO	DOD	9/97	None
<i>Investigation of a Suspected Outbreak of an Unknown Disease among Veterans of Operation Desert Shield/Desert Storm, 123rd Army Reserve Command (general health symptoms, medical and psychological conditions, laboratory screening)</i>	WRAIR	DOD	Complete	41
<i>Investigation of Symptomatic Illness in Naval Mobile Construction Battalion 24, November 1993-February 1994 (general health symptoms, review of medical records)</i>	Navy Environmental and Preventive Medicine Unit #2, Norfolk VA	DOD	Complete	10

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**GROUP I (cont.)**


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<i>A Statistical Study Correlating the Reported Cases of Gulf War Syndrome to Battlefield Locations of Afflicted U.S. Army Personnel During the Iraq-Kuwait War-Part I: Method to Relate Troop Deployment and the Reported Cases of Gulf War Syndrome and Probable Incidence of Maladies Defined by the ICD-9-CM (statistical techniques)</i>	U.S. Army Research Laboratory, Aberdeen, MD	DOD	Complete	72
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**GROUP II: Health Outcomes from Service in the Gulf War**

<i>Epidemiologic Studies of Morbidity among Gulf War Veterans: A Search for Etiologic Agents and Risk Factors-Study 4: Infertility and Miscarriage in Gulf War Veterans</i>	NHRC	DOD	9/97	None
<i>Feasibility of Investigating Whether There is a Relationship between Birth Defects and Service in the</i>	March of Dimes, California	DOD	6/98	None



Gulf War (birth defects in children of Gulf War veterans in California)	Birth Defects Monitoring Program			
<b>Suspected Increase of Birth Defects and Health Problems</b> among Children Born to Persian Gulf Veterans in Mississippi	Mississippi State Department of Health	DHHS	Complete	195
Epidemiologic Studies of Morbidity among Gulf War Veterans: A Search for Etiologic Agents and Risk Factors-Study 3: A Comparative Study of <b>Pregnancy Outcomes</b> among Gulf War Veterans and Other Active Duty Personnel	NHRC	DOD	Complete	36
Epidemiologic Studies of Morbidity Among Gulf War Veterans: A Search for Etiologic Agents and Risk Factors-Study 7: Prevalence of <b>Congenital Anomalies</b> among Children of Persian Gulf War Veterans	NHRC	DOD	6/97	None
Investigation of <b>Seminal Plasma Hypersensitivity</b> Reactions (immunological analysis of semen)	University of Cincinnati Medical Science Center	DOD	9/2000	None
Cutaneous Findings in Gulf War Veterans ( <b>dermatological</b> evaluations)	WRMC	DOD	Complete	123
<b>Diarrhea</b> in Persian Gulf Veterans: An <b>Irritable Bowel-Like Disorder</b>	VAMC Gainesville	VA	1/2000	None
<b>Chronic Gastrointestinal Illness</b> in Persian Gulf Veterans	VAMC Boston	VA	Complete	238
Study of <b>Mycoplasma</b> Infections in Gulf War Veterans	WRAIR	DOD	8/97	None
<b>Immunological</b> Evaluation of Persian Gulf Veterans	VAMC Birmingham	VA	Complete	None
The Symptomatic Persian Gulf Veterans Protocol: An Analysis of Risk Factors with an <b>Immunologic</b> and <b>Neuropsychiatric</b> Assessment	VAMC Birmingham	VA	12/99	120

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**GROUP II (cont.)**


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<b>Assessment of Genomic Instability</b> via Chromosome 7 Inversion Frequency in a Gulf War Syndrome Cohort v. Selected Control Groups (immunology)	Armed Forces Institute of Pathology	DOD	5/97	None
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<b>Evaluation of Respiratory Dysfunction Among Gulf War Veterans</b> (Kuwait oil-well fire effects)	VAMC Boston	VA	9/99	None
<b>Portland Environmental Hazards Research Center: Environment, Veterans Health and the Gulf War Syndrome-Project II. Clinical and Neuroendocrine Aspects of Fibromyalgia</b>	VAMC Portland	VA	9/99	None
<b>Musculoskeletal Symptoms in Gulf War Syndrome</b>	VAMC Long Beach	VA	1/99	None
<b>Evaluation of Muscle Function in Persian Gulf Veterans</b> (causes of chronic fatigue and muscle weakness)	University of Pennsylvania	DOD	11/99	None
<b>Evaluation of Neuromuscular Symptoms in Veterans of the Persian Gulf War</b> (neurological, neuromuscular, and psychiatric evaluations)	Wilford Hall Medical Center, TX	DOD	Complete	2
<b>Fatigue in Persian Gulf Syndrome-Physiologic Mechanisms</b> (physiology of muscle fatigue)	University of Texas	DOD	7/98	None
<b>Initial Contact Interview with Marine Reservists in Operation Desert Storm and 3-year Followup</b> (stress and PTSD outcomes)	VAMC Mountain Home	VA	3/97	231-236
<b>Neurobehavioral Aspects of Persian Gulf War Experiences: A Pilot Study</b> (stress, neuro-physiological and -psychological effects, PTSD outcomes)	VAMC Pittsburgh	VA	Complete	73
<b>A Comparison of PTSD Symptomology among Three Army Medical Units Involved in ODS</b>	VAMC Phoenix	VA	Complete	296
<b>Post-traumatic Stress Disorder Symptoms and Precombat Sexual and Physical Abuse in Desert Storm Veterans</b> (previous abuse, combat exposure, and PTSD)	Fort Hood Mental Health Clinic, TX	DOD	Complete	54
<b>Combat Stress Diagnosis, PTSD Prevention</b>	WRAIR	DOD	9/98	70,188
<b>Desert Storm Reunion Survey</b> (stress, PTSD outcomes)	VAMC Boston	VA	Complete	335-338
<b>Portland Environmental Hazards Research Center: Environment, Veterans Health and the Gulf War Syndrome-Project 1. Psychosocial, Neuropsychological, and Neurobehavioral Assessment</b> (stress, neuropsychological, PTSD outcomes)	VAMC Portland	VA	9/99	121

<i>Memory and Attention in PTSD</i> (neuropsychological outcomes)	VAMC New Orleans	VA	9/98	317-319
<b>Neuropsychological Functioning in Veterans</b> (stress and PTSD outcomes)	VAMC New Orleans	VA	Complete	317-319

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**GROUP II (cont.)**


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<b>Psychological Assessment of Operation Desert Storm Returnees</b> (stress, general health symptoms, depression, and PTSD outcomes)	VAMC New Orleans	VA	9/97	250-255
<b>Evaluation of Cognitive Functioning In Persian Gulf Veterans Reporting War-related Health Problems</b> (stress, neuropsychological and PTSD outcomes)	VAMC New Orleans	VA	Complete	254
<b>Evaluation of Cognitive Functioning of Persian Gulf Veterans</b> (stress, depression, general health symptoms, PTSD outcomes)	VAMC Boston	VA	9/99	210,335-3
<b>MMPI-2 Profiles</b> [Minnesota Multiphasic Personality Inventory, version 2] of Symptomatic Persian Gulf Veterans (psychological conditions)	Wilford Hall Medical Center, TX	DOD	Complete	86
<b>Female Gender and Other Potential Predictors of Functional Health Status Among Persian Gulf Veterans</b> (stress, MCS, PTSD outcomes)	VAMC Boston	DOD	3/98	210,335-3
<b>Physiological and Psychological Assessments of Persian Gulf Veterans</b> (stress, viral/immunological, neurophysiological and neuropsychological assessments, CFS, MCS outcomes)	VAMC East Orange	VA	3/97	None
<b>Effects of Exertion and Chemical Stress on Persian Gulf Veterans</b> (CFS, MCS outcomes)	VAMC East Orange/VA	VA	9/99	None
<b>Evaluation of Neurological Functioning in Persian Gulf Veterans</b> (stress, CFS, MCS, PTSD outcomes)	VAMC Boston	VA	9/99	None
<b>Persian Gulf Illnesses: Preliminary Neurological Impressions</b> (neurological evaluations)	Madigan Army Medical Center, WA	DOD	Complete	181
<b>Validity of Computerized Tests</b> (assessment of neurophysiologic damage)	VAMC Boston	VA	9/99	122,332

<b>Psychological and Neurobiological Consequences of Gulf War Experience</b> (stress, PTSD outcomes)	West Haven VAMC	DOD	7/99	239,240
<b>Neuropsychological Functioning in Persian Gulf War Era Veterans</b> (stress outcomes, cognitive impairments, and CNS damage)	Boston University Medical Campus	DOD	6/99	None
<b>Dysregulation of the Stress Response in the Persian Gulf Syndrome (CFS, FM, psychiatric outcomes, abnormalities in neurohormones related to stress response)</b>	Georgetown University Medical Center	DOD	6/99	None
<b>Acute and Long-Term Impact of Deployment to Southwest Asia on the Physical and Mental Health of Soldiers and Their Families</b> (stress outcomes)	Ft. Detrick	DOD	9/98	None
<b>Stress Symptoms and Their Causal Attribution in Desert Storm Veterans</b>	VAMC Clarksburg	VA	12/96	None
<b>Post-traumatic Stress Symptoms Among Soldiers Exposed to Combat in the Persian Gulf</b> (combat exposure, stress reactions)	Army Medical Department, Bremerhaven, Germany	DOD	Complete	126
<b>An Exploration of Post-traumatic Stress Disorder in Reserve Forces Deployed During Desert Storm</b>	University of South Florida	VA	Complete	215

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**GROUP II (cont.)**


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<b>Symptoms of Post-traumatic Stress Disorder Following Recovery of War Dead</b> (followup of PTSD symptoms over time)	WRAIR/DOD	DOD	Complete	152,153
<b>Psychological and War Stress Symptoms among Deployed and Non-deployed Reservists Following the Persian Gulf War</b> (combat exposure, stress, PTSD, and depression)	Highland Drive Medical Center, Pittsburgh	VA	Complete	197,204
<b>Unit-Based Intervention for Gulf War Soldiers Surviving a SCUD Missile Attack: Program Description and Preliminary Findings</b> (combat exposure, PTSD, and depression)	Highland Drive Medical Center, Pittsburgh	VA	Complete	198,204
<b>Psychological Adjustment In Operation Desert Shield/Storm Veterans</b> (stress outcomes)	VAMC Gainesville	VA	Complete	237

**GROUP III: Risk Factors and Gulf War Veterans' Health**

<b>Persian Gulf Veterans Health Tracking System</b> (Kuwait oil fire smoke and other environmental exposures)	CHPPM	DOD	12/97	None
<b>Portland Environmental Hazards Research Center: Environment, Veterans Health, and the Gulf War Syndrome-Project IV. DNA Damage from Chemical Agents and Its Repair</b> (nitrogen mustard effects in human skin cultures)	VAMC Portland, OR	VA	9/99	116
<b>Chronic Organophosphorus Exposure and Cognition</b> (chemical weapon effects in lab. animals)	University of Georgia	DOD	5/98	None
<b>Carcinogenicity of Depleted Uranium Fragments</b>	ITRI	DOD	10/98	None
<b>Health Risk Assessment of Embedded Depleted Uranium: Behavior, Physiology, Histology, and Biokinetic Modeling</b>	AFFRI	DOD	9/97	None
<b>Kuwait Oil Fire Health Risk Assessment</b>	CHPPM	DOD	Complete	154,265
<b>Kuwait Oil Fires Troop Exposure Assessment Model</b>	CHPPM	DOD	12/96	265
<b>The Aromatic Hydrocarbon Receptor AhR as a Biomarker of Susceptibility</b> (exposure to Kuwaiti oil well fires and petroleum products)	VAMC Boston	VA	9/99	None
<b>Biomarkers of Susceptibility and Polycyclic Aromatic Hydrocarbon (PAH) Exposure in Urine and Blood Cell DNA from U.S. Army Soldiers Exposed to Kuwaiti Oil Well Fires</b>	NIH	DHHS	1/97	265
<b>Volatile Organic Compounds in the Blood of Persons in Kuwait during the Oil Fires</b>	CDC	DHHS	Complete	55
<b>Characteristics of Emissions from Heaters Burning Leaded Diesel Fuel in Unvented Tents</b>	ITRI	DOD	7/98	none
<b>Forward Deployable Diagnostics for Infectious Diseases</b>	NMRI, WRAIR, USAMRIID	DOD	9/2001	111,327
<b>Identification of the Genetic Factors Which Control Tropism in Leishmania</b>	Army Research Lab, Brazil	DOD	7/98	24,25

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**GROUP III (cont.)**

Protective Immunity in Experimental Visceral <b>Leishmaniasis</b>	VAMC San Antonio	VA	9/97	None
Vaccine-mediated Immunity Against <b>Leishmaniasis</b>	VAMC Cleveland	VA	9/99	81-83
Development of a <b>Leishmania</b> Skin Test Antigen	WRAIR	DOD	1/2000	243,244
Serologic Diagnosis of Viscerotropic <b>Leishmaniasis</b>	WRAIR	DOD	Complete	45-47
Diagnostic Antigens of <b>Leishmania tropica</b>	Infectious Disease Research Institute, Seattle	DOD	6/98	None
Assessment of the Health of Workers Formerly Employed at Ft. Detrick Who Received Repeated <b>Immunizations</b> with <b>Multiple Vaccines</b> -Study I	USAMRIID	DOD	11/98	None
<b>Anthrax and Botulinum Vaccines:</b> Antibody Prevalence and Immune Response to a Booster Dose in Military Personnel Initially Vaccinated During Desert Shield/Desert Storm	USAMRIID	DOD	Complete	202b
Combat <b>Stress</b> Pharmacotherapy	WRAIR	DOD	9/99	79,80,206 9
Neurobehavioral and Immunological Toxicity of <b>Pyridostigmine, Permethrin and DEET</b> in Males and Females (immune and neurobehavioral effects of PB, DEET, and permethrin in rats)	University of Florida, Gainesville	DOD	5/99	None
Effects of Genetics and <b>Stress</b> on Responses to <b>Environmental Toxins</b> (stress as a mediating factor for effects of PB in rats)	VAMC East Orange	VA	9/97	196
Effects of <b>PB</b> in Flinders Line Rats Differing in Cholinergic Sensitivity (genetic effects in rats)	University of North Carolina, Chapel Hill	DOD	7/98	None
Physiological and Neurobehavioral Effects in Rodents from Exposure to <b>Pyridostigmine, Fuels, and DEET</b> -Toxicity of Simulated Persian Gulf War Exposure	Tri-service Toxicology Consortium, Wright Patterson AFB	DOD	10/97	180
Possible Relationship Between Multiple Chemical Sensitivity of Insect Repellent <b>DEET</b> and Carbamate <b>Pyridostigmine</b> in Gulf War Veterans' Illnesses: Study of Variability in	WRAIR	DOD	12/96	49,67,68

*Pyridostigmine Inhibition of Blood Cholinesterases in Healthy Adults*  
(interactions of PB with various pesticides in humans)

<b>Pyridostigmine Synergistic Toxicity Study</b> (interaction of PB and various pesticides in humans)	CHPPM	DOD	Complete	151,263
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*Portland Environmental Hazards Research Center: Environment, Veterans Health and the Gulf War Syndrome-Project III. Neurotoxicity of Environmental Pollutants and Warfare Agents* (effects of PB and hydrocarbon solvents on rodent nervous system)

VAMC Portland, OR	VA	9/99	50
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*Male/Female Differential Tolerances to Pyridostigmine Bromide* (humans)

South Florida Drug Research and Clinical Research Services	DOD	Complete	128
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### GROUP III (cont.)

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*Retrospective Studies Involving Military Use of Pyridostigmine as a Pretreatment for Nerve Agent Poisoning* (humans)

USAMRMC	DOD	Complete	270
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*Pyridostigmine Used as a Nerve Agent Pretreatment Under Wartime Conditions* (humans)

USAMRIC	DOD	Complete	110c
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*Effects of Persian Gulf War Service on Military Working Dogs*

AFIP	DOD	12/98	None
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*Use of Roster of Veterans Who Served in Persian Gulf Area*

EES, U.S. Army, and the Joint Services Environmental Support Group	VA	Complete	None
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a Abbreviations: AFFRI Armed Forces Radiobiology Research Institute, Bethesda, MDCCEP Comprehensive Clinical Evaluation Program CDC Centers for Disease Control and Prevention CFS Chronic Fatigue Syndrome CHPPM U.S. Army Center for Health Promotion and Preventive Medicine, Aberdeen, MD DHHS Department of Health and Human Services DOD Department of Defense EES VA Environmental Epidemiology Service FM Fibromyalgia ITRI Inhalation Toxicology Research Institute, Albuquerque, NM MCS Multiple Chemical Sensitivity NHRC Naval Health Research Center, San Diego, CANMRI Naval Medical Research Institute, Bethesda, MDPB pyridostigmine bromide PTSD Post-traumatic Stress Disorder UK United Kingdom USAEHA U.S. Army Environmental Hygiene Agency (now CHPPM) USAMRIC U.S. Army Medical Research Institute of Chemical Defense USAMRIID U.S. Army Medical Research Institute of Infectious Diseases USAMRMC U.S.

Army Medical Research and Materiel CommandVA Department of Veterans AffairsVAMC Veterans  
Affairs Medical CenterWRAIR Walter Reed Army Institute of Research, Washington, DCWRMC  
Walter Reed Medical Center, Washington, DC

b Considerable general vaccine research concerning botulinum and anthrax vaccines is  
c Before and after the Gulf War, DOD has conducted research on PB in conjunction wit



## Presidential Advisory Committee on Gulf War Veterans' Illnesses Final Report

### APPENDIX G - FINDINGS OF THE ADVISORY COMMITTEE'S *INTERIM REPORT*

#### OUTREACH

- DOD's Persian Gulf Medical Registry Hotline and VA's Persian Gulf Helpline effectively educate callers about the availability of the CCEP and the Persian Gulf Health Registry, respectively. Both telephone systems adequately refer callers to points of contact at medical treatment facilities.
- DOD's GulfLINK offers a user friendly, accessible resource that deposits information pertinent to Gulf War veterans' illnesses in a central location.
- Since GulfLINK contains contradictory intelligence reports, the net effect of posting these declassified documents on GulfLINK could be to confuse rather than enlighten the interested public. Without a better system for organizing and presenting information, persons using the resource could gain false impressions or misunderstand documents.
- Although mailings such as the memorandum from Secretary Perry and Chairman Shalikashvili can be expensive, they are a reasonable method of getting information to the concerned population.
- VA's On-line service and World Wide Web home page provide computer users with a widely accessible Gulf War veterans' illness education and referral resource.
- VA's print PSA gives readers useful information on Gulf War veterans' illnesses. VA's broadcast PSAs, which publicize the Helpline number but do not mention illness or potential illness as a reason to call, need improvement.
- VA's use of the term "priority care" in reference to Gulf War veterans' eligibility for health care creates false expectations among a significant portion of its clientele.
- Public and congressional concern for the health of Gulf War veterans has been evident since the world witnessed the 1991 oil well fires on television. DOD did not set up hotlines or sites at medical treatment facilities to provide information and medical referral services to Gulf War veterans until 1994, a significant delay in response time.
- VA's Helpline started late in comparison with its other efforts to address the issue of Gulf War veterans' illnesses. It was established two years after the initiation of the Persian Gulf Health Registry and one year following the passing of Public Law 103-210, which initiated "priority care" services. VA had conducted some outreach in tandem with the establishment of the Health Registry, but its *Persian Gulf Review* newsletter was sent only to those already participating in the Health Registry.

#### MEDICAL AND CLINICAL ISSUES

- No uniformity existed among the services in their predeployment or demobilization policies and procedures at the time of Operations Desert Shield/Desert Storm.
- There is little evidence that quality control procedures were employed to ensure that existing policies were actually carried out during deployment or demobilization.
- DOD's policies and procedures were not adequate in all cases to prevent members with preexisting conditions from deploying or to identify health problems extant at the time of demobilization, and these conditions could have contributed to some current health concerns.
- FDA and DOD undertook an urgent and orderly course of action under the circumstances to devise a means to address the real threat of chemical and biological warfare in the Gulf War.
- FDA has not been proactive in addressing public comments on the interim final rule or in devising better long-term methods for governing military use of drugs, vaccines, devices, and antibiotics intended for chemical and biological warfare defense.
- When a waiver of informed consent is granted, the government has a strong obligation to conduct long-term followup of military personnel who receive investigational products.
- DOD did not keep adequate records on who received anthrax and BT vaccines and PB in the Gulf War theater. There is little possibility now of developing reliable data about which or how many

persons received those products.

- DOD and VA admit to problems with missing or lost medical records, but neither system appears to place a priority on correcting these problems.
- DOD's rationale for the requirement that records of vaccinations be kept secret was not well understood. This requirement confused and complicated recordkeeping procedures and hindered systematic followup of health issues.
- The issue of accurate medical and vaccination records is central to the concerns of many ill veterans, and the absence of records has been suggested by some as evidence that the government is engaging in a cover-up of its own predeployment practices.

## RESEARCH

- Despite the unique features of the Gulf War, it should be possible using epidemiologic approaches to determine whether Gulf War veterans have more or less mortality, symptoms, or diseases than an appropriately chosen comparison population.
- Most of the studies examined by the Committee appear to be well-designed and appropriate to answer questions about mortality, symptoms, or diseases.
- Some studies currently underway or planned at best will add little information to other better designed studies and could provide misleading information, leading to false conclusions.
- External scientific review of the major epidemiologic studies has ranged from nonexistent, to one-time review of protocols, to standing scientific advisory panels which have an ongoing role in the design and execution of the studies. Ongoing external review has proved beneficial to several of the studies.
- Public advisory committees might improve communications with the veterans asked to participate in epidemiologic studies.
- A single coordinating body with an overarching perspective is needed to monitor whether priorities are being established, whether outstanding research questions are being adequately addressed, whether individual studies will contribute to the overall effort, and the extent to which the studies are responsive to recommendations from external reviewers.
- Sharing a subset of basic questions on demographics, symptoms, and exposures across large surveys of Gulf War veterans and controls could provide information useful for comparisons across the studies and better understanding of differences in the study populations.
- There is little exposure data available for Gulf War veterans about many key risk factors. As a consequence, it will be more difficult to link adverse health outcomes detected by epidemiologic studies to some specific exposures or risk factors.
- The Persian Gulf Registry of Unit Locations data from DOD will be important for investigating questions about Gulf War veterans' health issues, but it will not be a substitute for missing exposure data for many risk factors.

## CHEMICAL AND BIOLOGICAL WEAPONS

- Although much was known at the time of the Gulf War, UNSCOM's work provides a more definitive picture of Iraq's CBW capability and doctrine, revealing advanced capabilities and underscoring the considerable uncertainty regarding Iraq's intentions to use CBW agents against American and coalition troops.
- The U.S. government's decision to reexamine the records of the Gulf War for evidence of exposure to CBW agents is prudent in light of the health concerns of veterans and the findings from UNSCOM's investigations. The Committee intends to monitor the investigations of PGIT and CIA.
- DOD is taking reasonable steps to improve battlefield CW agent detection capability by developing equipment that will detect mustard agent and that will not sound false alarms in response to common battlefield interferents.
- The inability to provide real-time detection of BW agents constitutes a serious deficiency in the U.S. chemical and biological defense posture.
- The ability to monitor low-levels of CW agents would improve the health care surveillance of U.S. troops.

## **Appendix H - Acknowledgments**

During its tenure, the Advisory Committee was assisted in its work by invaluable contributions from the following individuals, who testified or gave public comment before the Committee, provided written statements, supplied information, or reviewed a draft of this report:

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Betty Zuspann

**Presidential Advisory Committee on Gulf War Veterans' Illnesses  
Final Report**

**LIST OF ACRONYMS**

**ACADA** - Advanced Chemical Agent Detector/Alarm

**AFIS** - American Forces Information Services

**AFRTS** - Armed Forces Radio and Television Service

**ATSDR** - Agency for Toxic Substances and Disease Registry (DHHS)

**BAA** - Broad Agency Announcement

**BT** - botulinum toxoid

**BuChE** - butyryl cholinesterase

**BW** - biological warfare

**CBT** - cognitive-behavioral therapy

**CBW** - chemical and biological warfare

**CCEP** - Comprehensive Clinical Evaluation Program (DOD)

**CDC** - Centers for Disease Control (DHHS)

**CFS** - Chronic Fatigue Syndrome

**CHAMPUS** - Civilian Health and Medical Program of the Uniformed Services

**CIA** - Central Intelligence Agency

**CL** - cutaneous leishmaniasis

**CME** - Continuing Medical Education

**CNS** - central nervous system

**CW** - chemical warfare

**CWG** - Clinical Working Group

**DBWG** - Disabilities and Benefits Working Group

**DHHS** - Department of Health and Human Services

**DOD** - Department of Defense

**DOE** - Department of Energy

**DOL** - Department of Labor

**DSB** - Defense Science Board

**DU** - depleted uranium

**EEG** - electroencephalogram

**EPA** - Environmental Protection Agency

**FDA** - Food and Drug Administration (DHHS)

**FM** - fibromyalgia

**GAO** - General Accounting Office

**HI** - Hazard Indices

**IARC** - International Agency for Research on Cancer

**IND** - investigational new drug

**IOM** - Institute of Medicine

**IRB** - Institutional Review Board

**KTO** - Kuwaiti Theater of Operations

**MCS** - multiple chemical sensitivity

**MOU** - Memorandum of Understanding

**MSD** - musculoskeletal system disorder

**NCHS** - National Center for Health Statistics (DHHS)

**NCS** - National Comorbidity Survey

**NIH** - National Institutes of Health (DHHS)

**NIOSH** - National Institute for Occupational Safety and Health (DHHS)

**NRC** - National Research Council

**NVLSP** - National Veterans Legal Services Program

**OMB** - Office of Management and Budget

**OBS** - organic brain syndrome

**OPIDN** - organophosphate-induced delayed neurotoxicity

**PAH** - polycyclic aromatic hydrocarbon

**PB** - pyridostigmine bromide

**PGFSP** - Persian Gulf Family Support Program

**PGIT** - Persian Gulf Veterans' Illnesses Investigation Team (DOD)

**PRD** - Presidential Review Directive

**PSA** - Public Service Announcement

**PTSD** - post-traumatic stress disorder

**RCS** - Readjustment Counseling Service (VA)

**RWG** - Research Working Group

**SCE** - sister chromatid exchange

**SSIDC** - Symptoms, Signs, and Ill-defined Conditions

**TAP** - Transition Assistance Program

**TBE** - tick borne encephalitis

**UNSCOM** - United Nations Special Committee (on Iraq)

**VA** - Department of Veterans Affairs

**VAMC** - Veterans Administration Medical Center

**VL** - viscerotropic leishmaniasis

**VOC** - volatile organic compound

**VSO** - veterans service organization

**WWI** - World War I

**WWII** - World War II